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

1.1. Product identifier

Product form: Mixture
Product name: Sil-Select Plus
Sil-Select Plus with phenol red
Sil-Select Plus with gentamicin
Sil-Select Plus with phenol red and 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: Gradient system for semen preparation

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
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>&lt; 55</td>
<td>Not classified</td>
</tr>
<tr>
<td>Silica Basic Solution (SIBO)</td>
<td></td>
<td>45 (SIP Upper Layer) 90 (SIP Lower Layer) 80 (SIP 80%)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>(CAS-No.) 7647-14-5 (EC-No.) 231-598-3</td>
<td>&lt; 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>HEPES</td>
<td>(CAS-No.) 7365-45-9 (EC-No.) 230-907-9</td>
<td>&lt; 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Human serum albumin</td>
<td>(CAS-No.) 70024-90-7</td>
<td>&lt; 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium lactate</td>
<td>(CAS-No.) 867-66-1 (EC-No.) 212-762-3</td>
<td>&lt; 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Glucose monohydrate</td>
<td>(CAS-No.) 14431-43-7</td>
<td>&lt; 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium Hydrogen Carbonate</td>
<td>(CAS-No.) 144-55-8 (EC-No.) 205-633-8</td>
<td>&lt; 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Potassium Chloride</td>
<td>(CAS-No.) 7447-40-7 (EC-No.) 231-211-8</td>
<td>&lt; 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Calcium chloride dihydrate</td>
<td>(CAS-No.) 10035-04-8</td>
<td>&lt; 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; 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Magnesium Sulphate Heptahydrate</td>
<td>(CAS-No.) 10034-99-8</td>
<td>&lt; 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium Pyruvate</td>
<td>(CAS-No.) 113-24-6 (EC-No.) 204-024-4</td>
<td>&lt; 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>If applicable, Gentamicin sulfate</td>
<td>(CAS-No.) 1405-41-0</td>
<td>&lt; 1</td>
<td>Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 1A, H369</td>
</tr>
<tr>
<td>If applicable, Phenol red sodium salt</td>
<td>(CAS-No.) 34487-61-1</td>
<td>&lt; 1</td>
<td>Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335</td>
</tr>
</tbody>
</table>

Full text of H-statements: see section 16

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

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

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

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

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/effects: 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 the environment.

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment: Equip cleanup crew with proper protection.

Emergency procedures: Ventilate area.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: 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 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 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.

Incompatible materials: Sources of ignition. Direct sunlight.

Storage temperature: 2-8 °C.

7.3. Specific end use(s)

No additional information available
SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

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

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

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

**Hand protection:**
Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove’s outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
The selected protective gloves have to meet specifications of regulation EU 2016/425 and the standard EN374.

**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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>Bluish hazy solution. When product contains phenol red: reddish hazy solution</td>
</tr>
<tr>
<td>Odour</td>
<td>Odourless</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>7.2-7.9 (release criteria: 7.2-7.6)</td>
</tr>
<tr>
<td>Relative evaporation rate (butylacetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Non flammable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density at 20 °C</td>
<td>No data available</td>
</tr>
</tbody>
</table>
## Sil-Select Plus (with phenol red and/or gentamicin)

### Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

<table>
<thead>
<tr>
<th>Property</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative density</td>
<td>SIP Lower Layer: 1.1050-1.1150 g/ml</td>
</tr>
<tr>
<td></td>
<td>SIP 80%: 1.097-1.107 g/ml</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Partition coefficient n-octanol/water (Log Pow)</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>For SIP Lower Layer and 80%: &lt;1.65cP</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive limits</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 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 sunlight. Extremely high or low temperatures.

#### 10.5. Incompatible materials

Strong acids. Strong bases.

#### 10.6. Hazardous decomposition products


### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

- **Acute toxicity (oral)**: Not classified
- **Acute toxicity (dermal)**: Extensive data on Sperm Survival tests have demonstrated that the medium is not toxic.
- **Acute toxicity (inhalation)**: The product has been evaluated for its toxicity by an independent test laboratory using the AGAR diffusion test. The medium meets the requirements of the ISO 10993-5 guidelines

- **Skin corrosion/irritation**: Not classified
- **Additional information**: Based on available data, the classification criteria are not met. The product has been evaluated for its irritating potential by and independent test laboratory using the primary vaginal test-repeated exposure. The medium meets the requirements of the ISO 10993-10 guidelines

- **Serious eye damage/irritation**: Not classified
- **Additional information**: Based on available data, the classification criteria are not met

- **Respiratory or skin sensitisation**: Not classified
- **Additional information**: Based on available data, the classification criteria are not met. The product has been evaluated for its sensitizing potential by and independent test laboratory using the Kligman maximization test. The medium meets the requirements of the ISO 10993 guidelines

- **Germ cell mutagenicity**: Not classified
- **Additional information**: Based on available data, the classification criteria are not met

- **Carcinogenicity**: Not classified
- **Additional information**: Based on available data, the classification criteria are not met
Reproductive toxicity: Not classified
Additional information: Based on available data, the classification criteria are not met

STOT-single exposure: Not classified
Additional information: The product has been evaluated for its biological reaction by an independent test laboratory using the systemic injection test (single dose). The medium meets the requirements of the ISO 10993 guidelines

STOT-repeated exposure: Not classified
Additional information: Based on available data, the classification criteria are not met

Aspiration hazard: Not classified
Additional information: Based on available data, the classification criteria are not met

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**

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

**12.2. Persistence and degradability**

Sil-Select Plus (with phenol red and/or gentamicin)
Persistence and degradability: Not established.

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

**12.3. Bioaccumulative potential**

Sil-Select Plus (with phenol red and/or gentamicin)
Bioaccumulative potential: Not established.

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

**12.4. Mobility in soil**

No additional information available

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

No additional information available

**12.6. Other adverse effects**

Additional information: Avoid release to the environment.
SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

SECTION 14: Transport information

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

14.1. UN number

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

14.2. UN proper shipping name

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

14.3. Transport hazard class(es)

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

14.4. Packing group

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

14.5. Environmental hazards

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

14.6. Special precautions for user

| Overland transport | Not applicable |
| Transport by sea | Not applicable |
| Air transport | Not applicable |
Inland waterway transport
Not applicable

Rail transport
Not applicable

14.7. Transport in bulk according to Annex II of Marpol 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
Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany
Water hazard class (WGK) : WGK 2, Significantly hazardous to water (Classification according to AwSV, Annex 1)
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

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

15.2. Chemical safety assessment
No chemical safety assessment has been carried out

SECTION 16: Other information


Other information : None.

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

Full text of H- and EUH-statements:

- **Eye Irrit. 2**
  - Serious eye damage/eye irritation, Category 2

- **Repr. 1A**
  - Reproductive toxicity, Category 1A

- **Resp. Sens. 1**
  - Respiratory sensitisation, Category 1

- **Skin Irrit. 2**
  - Skin corrosion/irritation, Category 2

- **Skin Sens. 1**
  - Skin sensitisation, Category 1

- **STOT SE 3**
  - Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
**Sil-Select Plus (with phenol red and/or gentamicin)**

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H315</td>
<td>_H_315_EU : Causes skin irritation</td>
</tr>
<tr>
<td>H317</td>
<td>_H_317_EU : May cause an allergic skin reaction</td>
</tr>
<tr>
<td>H319</td>
<td>_H_319_EU : Causes serious eye irritation</td>
</tr>
<tr>
<td>H334</td>
<td>_H_334_EU : May cause allergy or asthma symptoms or breathing difficulties if inhaled</td>
</tr>
<tr>
<td>H335</td>
<td>_H_335_EU : May cause respiratory irritation</td>
</tr>
<tr>
<td>H360</td>
<td>_H_360_EU : May damage fertility or the unborn child</td>
</tr>
</tbody>
</table>

**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.