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

1.1. Product identifier
   Product form: Mixture
   Product name: SpermMar IgG: Latex bead solution
   Antiserum
   Product code: SPMG_L / SPMG_AS
   GMDN code: 30486

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: Diagnostic test kit for the detection of sperm antibodies of the IgG class in human semen

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
   According to EC directives or the corresponding national regulations there is no labelling obligation for this product.

2.3. Other hazards
   No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance
   Not applicable

3.2. Mixture

3.2.2 SpermMar IgG- Latex bead solution

<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</td>
<td>90 - 99</td>
<td>Not classified</td>
</tr>
<tr>
<td></td>
<td>(EC no) 231-791-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>(CAS No) 7647-14-5</td>
<td>0.1 - 1</td>
<td>Not classified</td>
</tr>
<tr>
<td></td>
<td>(EC no) 231-598-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycine</td>
<td>(CAS No) 56-42-6</td>
<td>0.1 - 1</td>
<td>Not classified</td>
</tr>
<tr>
<td></td>
<td>(EC no) 200-272-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polystyrene latex particles coated with human protein</td>
<td>(CAS No) 9003-53-6</td>
<td>0.1 - 1</td>
<td>Not classified</td>
</tr>
<tr>
<td>Bovine serum albumin</td>
<td>(CAS No) 9048-46-8</td>
<td>0.1 - 1</td>
<td>Not classified</td>
</tr>
<tr>
<td></td>
<td>(EC no) 232-936-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>(CAS No) 1310-73-2</td>
<td>0.1 - 1</td>
<td>Skin Corr. 1A, H314</td>
</tr>
<tr>
<td></td>
<td>(EC no) 215-185-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(EC index no) 011-002-00-6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### SpermMar IgG: Latex bead solution

#### Antiserum

**Safety Data Sheet**

according to Regulation (EC) No. 453/2010

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**3.2.2 SpermMar IgG- Antiserum**

<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 Azide</td>
<td>(CAS No) 26628-22-8</td>
<td>&lt; 0.1</td>
<td>Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>(CAS No) 1310-73-2</td>
<td>(0,5 &lt;= C &lt; 2)</td>
<td>Skin Irrit. 2, H315 (0.5 &lt;= C &lt; 2) Eye Irrit. 2, H319 (2 &lt;= C &lt; 5) Skin Corr. 1B, H314 (C &gt;= 5) Skin Corr. 1A, H314</td>
</tr>
</tbody>
</table>

Full text of H-phrases: see section 16

---

### 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

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### 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.

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### SECTION 6: Accidental release measures

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

**For non-emergency personnel**: Evacuate unnecessary personnel.

**For emergency responders**: Equip cleanup crew with proper protection.

#### 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

<table>
<thead>
<tr>
<th>Storage conditions</th>
<th>Keep only in the original container in a cool place away from direct (sun)light. Keep container closed when not in use. Do not freeze. Do not use after expiry date.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incompatible products</td>
<td>Strong bases. Strong acids.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Sources of ignition. Direct (sun)light.</td>
</tr>
<tr>
<td>Storage temperature</td>
<td>2 - 8 °C</td>
</tr>
</tbody>
</table>

#### 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**

**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

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Latex Bead Solution: White Antiserum: yellow</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>Latex Bead solution: 8 - 9</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>
</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. 14 days) at elevated (≤37°C) temperature. Stable for 18 months from date of manufacturing.

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
Irritation : Not classified
Corrosivity : Not classified
Sensitisation : Not classified
Repeated dose toxicity : Not classified
Carcinogenicity : Not classified
Mutagenicity : Not classified
Toxicity for reproduction : Not classified
Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.
Other information : Materials from which the Human serum were manufactured, were found non-reactive for HIV, HCV and HBsAg when tested with licensed reagents. However, no known test method can assure that infectious agents are absent. Products from human blood origin should be considered as potentially infectious.

SECTION 12: Ecological information

12.1. Toxicity
No additional information available

12.2. Persistence and degradability
SpermMar IgG - Latex bead solution
Persistence and degradability : Not established.

12.3. Bioaccumulative potential
SpermMar IgG - Latex bead solution
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

#### 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)**: Not applicable
- **IMDG: Transport hazard class(es)**: Not applicable
- **IATA: Transport hazard class(es)**: Not applicable
- **ADN: Transport hazard class(es)**: Not applicable
- **RID: Transport hazard class(es)**: 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
SpermMar IgG: Latex bead solution Antiserum
Safety Data Sheet according to Regulation (EC) No. 453/2010

Data sources:

Other information:
None.

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

Full text of H- and EUH-phrases:

<table>
<thead>
<tr>
<th>Acute Toxic. 2 (Oral)</th>
<th>Acute toxicity (oral), Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute 1</td>
<td>Hazardous to the aquatic environment — Acute Hazard, Category 1</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>Hazardous to the aquatic environment — Chronic Hazard, Category 1</td>
</tr>
<tr>
<td>Skin Corr. 1A</td>
<td>Skin corrosion/irritation, Category 1A</td>
</tr>
<tr>
<td>H300</td>
<td>Fatal if swallowed</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects</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.