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

1.1. Product identifier
Product name: SpermMar IgG: Positive and Negative control
Product Code: SPMG_N / SPMG_P
GMDN Code: 42222

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: SpermMar IgG is a diagnostic 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

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>FertiCult Flushing Medium without HSA</td>
<td>-</td>
<td>90 - 99</td>
<td>Not classified</td>
</tr>
<tr>
<td>Human Serum</td>
<td>-</td>
<td>5 - 10</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium Azide</td>
<td>(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7</td>
<td>&lt; 0,1</td>
<td>Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410</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.
SpermMar IgG - Positive and Negative control
Safety Data Sheet
according to Regulation (EC) No. 453/2010

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.
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 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.
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
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.

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Colour : White, transparent
Odour : Odourless
Odour threshold : No data available
pH : No data available
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 : 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 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
SpermMar IgG - Positive and Negative control
Safety Data Sheet
according to Regulation (EC) No. 453/2010

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.

SECTION 12: Ecological information

12.1. Toxicity
No additional information available

12.2. Persistence and degradability
Spermar IgG- Positive and Negative control
Persistence and degradability: Not established.

12.3. Bioaccumulative potential
Spermar IgG- Positive and Negative control
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
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
SpermMar IgG - Positive and Negative control
Safety Data Sheet
according to Regulation (EC) No. 453/2010

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:

| Acute Tox. 2 (Oral) | Acute toxicity (oral), Category 2 |
| Acquatic Acute 1 | Hazardous to the aquatic environment — Acute Hazard, Category 1 |
| Acquatic Chronic 1 | Hazardous to the aquatic environment — Chronic Hazard, Category 1 |
| 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 |
| H300 | Fatal if swallowed |
| 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 |
| H400 | Very toxic to aquatic life |
| H410 | Very toxic to aquatic life with long lasting effects |

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.