SpermMar Test IgG: Positive and Negative control

Safety Data Sheet
according to Regulation (EC) No. 453/2010
Id: FP09 I02b R02
Revision date: 14/10/2019

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

1.1. Product identifier
Product form : Mixture
Product name : SpermMar Test 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 : The SpermMar Test IgG Positive and Negative Control are designed to be used as quality control with the SpermMar Test IgG.

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>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.
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.

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
General measures: Remove ignition sources. Use special care to avoid static electric charges. No open fire. Do not smoke.

6.1. For non-emergency personnel
Emergency procedures: Evacuate unnecessary personnel.

6.1. 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: Soak up spills as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections
See Section 8. Exposure controls/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.
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: Wear fire/flame resistant retardant clothing.
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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 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>White, transparent</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>No data available</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>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Pow</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</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 (≤37°C) temperature. 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. Open fire.

10.5. Incompatible materials
Strong acids. Strong bases.

10.6. Hazardous decomposition products
Smoke. Carbon monoxide. Carbon dioxide.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Specific target organ toxicity (single exposure)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Specific target organ toxicity (repeated exposure)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Not classified</td>
</tr>
<tr>
<td>Potential adverse human health effects and symptoms</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>Other information</td>
<td>Materials from which the human serum was 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.</td>
</tr>
</tbody>
</table>

SECTION 12: Ecological information

12.1. Toxicity
No additional information available

12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>SpermMar Test IgG- Positive and Negative control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistence and degradability</td>
</tr>
</tbody>
</table>

12.3. Bioaccumulative potential

<table>
<thead>
<tr>
<th>SpermMar Test IgG- Positive and Negative control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioaccumulative potential</td>
</tr>
</tbody>
</table>

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
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)

<table>
<thead>
<tr>
<th>Transport hazard class(es) (ADR)</th>
<th>Not applicable</th>
</tr>
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<tbody>
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<td>Transport hazard class(es) (IATA)</td>
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<td>Transport hazard class(es) (ADN)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Transport hazard class(es) (RID)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

14.4. Packing group

| Packing group (ADR)                                     | Not applicable |

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<table>
<thead>
<tr>
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</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:
- Acute Tox. 2 (Oral): Acute toxicity (oral), Category 2
- Aquatic Acute 1: Hazardous to the aquatic environment — Acute Hazard, Category 1
- Aquatic Chronic 1: Hazardous to the aquatic environment — Chronic Hazard, Category 1
- H300: Fatal if swallowed
- 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.