

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 Directive 67/548/EEC or 1999/45/EC

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

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Ultrapure water	(CAS No) 7732-18-5 (EC no) 231-791-2	90 - 99	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (EC no) 231-598-3	0,1 - 1	Not classified
Glycine	(CAS No) 56-40-6 (EC no) 200-272-2	0,1 - 1	Not classified
Polystyrene latex particles coated with human protein	(CAS No) 9003-53-6	0,1 - 1	Not classified
Bovine serum albumin	(CAS No) 9048-46-8 (EC no) 232-936-2	0,1 - 1	Not classified
Sodium Hydroxide	(CAS No) 1310-73-2 (EC no) 215-185-5 (EC index no) 011-002-00-6	0,1 - 1	C; R35

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Name	Product identifier	%	Classification according to Directive 67/548/EEC
Sodium Azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0,1	T+; R28 R32 N; R50/53
Name	Product identifier	Specific concentration limits	
Sodium Hydroxide	(CAS No) 1310-73-2 (EC no) 215-185-5 (EC index no) 011-002-00-6	(0,5 =< C < 2) Xi;R36/38 (2 =< C < 5) C;R34 (C >= 5) C;R35	
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ultrapure water	(CAS No) 7732-18-5 (EC no) 231-791-2	90 - 99	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (EC no) 231-598-3	0,1 - 1	Not classified
Glycine	(CAS No) 56-40-6 (EC no) 200-272-2	0,1 - 1	Not classified
Polystyrene latex particles coated with human protein	(CAS No) 9003-53-6	0,1 - 1	Not classified
Bovine serum albumin	(CAS No) 9048-46-8 (EC no) 232-936-2	0,1 - 1	Not classified
Sodium Hydroxide	(CAS No) 1310-73-2 (EC no) 215-185-5 (EC index no) 011-002-00-6	0,1 - 1	Skin Corr. 1A, H314
Sodium Azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0,1	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Name	Product identifier	Specific concentration limits	
Sodium Hydroxide	(CAS No) 1310-73-2 (EC no) 215-185-5 (EC index no) 011-002-00-6	(0,5 =< C < 2) Skin Irrit. 2, H315 (0,5 =< C < 2) Eye Irrit. 2, H319 (2 =< C < 5) Skin Corr. 1B, H314 (C >= 5) Skin Corr. 1A, H314	

3.2.2 SpermMar IgG- Antiserum

Name	Product identifier	%	Classification according to Directive 67/548/EEC
N Antiserum IgG	-	100	Not classified

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
N Antiserum IgG	-	100	Not classified

Full text of R- and 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.
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4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Dry powder. Carbon dioxide. Water spray. Sand. Foam.
Unsuitable extinguishing media	: Do not use a heavy water stream.

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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. 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 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

Personal protective equipment : Avoid all unnecessary exposure.

Hand protection : Wear protective gloves.

Eye protection : Chemical goggles or safety glasses.

Respiratory protection : Wear appropriate mask.

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 : Latex Bead Solution: White
Antiserum: yellow

Odour : Odourless

Odour threshold : No data available

pH : Latex Bead solution: 8 - 9

Relative evaporation rate (butylacetate=1) : No data available

Melting point : No data available

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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 after transport (max. 14 days) at elevated ($\leq 37^{\circ}\text{C}$) 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

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Persistence and degradability	Not established.

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12.3. Bioaccumulative potential

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Bioaccumulative potential	Not established.
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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

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

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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

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

Not classified	
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Full text of R-, 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
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
H300	Fatal if swallowed
H314	Causes severe skin burns and eye damage
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
R28	Very toxic if swallowed
R32	Contact with acids liberates very toxic gas
R35	Causes severe burns
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
C	Corrosive
N	Dangerous for the environment
T+	Very toxic

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