

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

1.1. Product identifier

Product form : Mixture
 Product name : SpermMar Test IgA
 Product code : SPMA_S
 SPMA_C
 GMDN : 55181

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 kit for the detection of sperm antibodies of the IgA 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 NV
 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

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

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
Latex beads coated with anti-IgA	/	1 - 5	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
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	Skin Corr. 1A, H314

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
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 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

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 (5 ≤ C < 100) Skin Corr. 1A, H314

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. Wash affected clothing before reuse.
- First-aid measures after eye contact : Remove contact lenses, if possible. 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

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- 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.

6.1.1. 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 : 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.

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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, well ventilated place away from (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. Heat sources.

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

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye and 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).
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8.2.2.2. Skin protection

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.

8.2.2.3. Respiratory protection

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).
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8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use. Do not pipette using a mouth pipette.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: White
Odour	: Odourless
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability (solid, gas)	: Non flammable
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7,6-9
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50 °C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20 °C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

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 ($\leq 37^{\circ}\text{C}$) temperature. Stable for 12 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. Open fire.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Smoke. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified

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

Sodium azide (26628-22-8)

STOT-repeated exposure	_H_373_EU.
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Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information available

11.2.2. Other information

Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met
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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

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

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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Sodium Chloride (7647-14-5)

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. Endocrine disrupting properties

No additional information available

12.7. 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.

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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 / RID / IMDG / IATA / ADN) : Not applicable

14.3. Transport hazard class(es)

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

14.4. Packing group

Packing group (ADR / RID / IMDG / IATA / ADN) : 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

No data available

Transport by sea

No data available

Air transport

No data available

Inland waterway transport

No data available

Rail transport

No data available

14.7. Maritime transport in bulk according to IMO instruments

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

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

France	
Occupational diseases	
Code	Description
RG 78	Diseases caused by sodium chloride in salt mines and their dependencies

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

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NON-exhaustive list of reproductive toxins - Breastfeeding : 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

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage Class (LK) : LK 10/12 - Liquids

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.

Full text of H- and EUH-phrases:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
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
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H300	Fatal if swallowed
H310	Fatal in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H319	Causes serious eye irritation
H330	Fatal if inhaled
H373	May cause damage to organs through prolonged or repeated exposure
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