

Safety Data Sheet

SpermFilter® Ready-to-use gradient 80% / 45%

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878



Date Issued: 14-05-2024
Revision No.: 328/02
Page: 1/11

1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product form: Mixture
Product name: SpermFilter® Ready-to-use gradient 80% / 45%
Product number: SPF45-0010, SPF45-0050, SPF45-0100, SPF45-0250, SPF45-0500
SPF80-0010, SPF80-0050, SPF80-0100, SPF80-0250, SPF80-0500

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: Gradient system for semen preparation

1.2.2. Uses advised against

No additional information available

1.3 Details of the supplier of the safety data sheet

Manufacturer: FertiPro NV
Industriepark Noord 32
8730 Beernem
Belgium
info@fertipro.com

Exclusive distributor: Gynotec B.V.
Jonckherenhof 7
6581 GC Malden
The Netherlands
info@gynotec.com

1.4 Emergency telephone number

For emergency information: +31 243586582

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008
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

Safety Data Sheet

SpermFilter[®] Ready-to-use gradient 80% / 45%

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Revision No.: 328/02
Page: 2/11

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.

3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance

Not applicable

3.2 Mixture

Component	Product identifier	Approx. %	Classification according to Regulation (EC) No. 1272/2008
Ultrapure water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	< 55	Not classified
Calcium chloride dihydrate	(CAS-No.) 10035-04-8	< 0.1	Eye Irrit. 2, H319
Potassium chloride	(CAS-No.) 7447-40-7 (EC-No.) 231-211-8	< 0.1	Not classified
Magnesium sulphate heptahydrate	(CAS-No.) 10034-99-8	< 0.1	Not classified
Sodium chloride	(CAS-No.) 7647-14-5 (EC-No.) 231-598-3	< 1	Not classified
Sodium dihydrogen phosphate dihydrate	(CAS-No.) 13472-35-0	< 0.1	Not classified
Glucose monohydrate	(CAS-No.) 14431-43-7	< 0.1	Not classified
Sodium hydrogen carbonate	(CAS-No.) 144-55-8 (EC-No.) 205-633-8	< 1	Not classified
Sodium pyruvate	(CAS-No.) 113-24-6 (EC-No.) 204-024-4	< 0.1	Not classified
HEPES	(CAS-No.) 7365-45-9 (EC-No.) 230-907-9	< 1	Not classified
Silica basic solution (SIBO)	not applicable	45 (45%) 80 (80%)	Not classified
Human Serum Albumin	(CAS-No.) 70024-90-7	< 1	Not classified
Sodium Lactate	(CAS-No.) Not determined (EC-No.) 212-762-3	< 1	Not classified
Gentamicin sulfate	(CAS-No.) 1405-41-0	< 0.1	Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 1A, H360
Phenol red sodium salt	CAS-No.) 34487-61-1	< 0.1	Skin. Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of H-statements:

See section 16

Safety Data Sheet

SpermFilter® Ready-to-use gradient 80% / 45%

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Revision No.: 328/02
Page: 3/11

The media do not contain any raw materials of direct animal-origin or materials that have been produced using TSE relevant animal-origin components. Components have not been in contact with material of animal origin during processing and therefore pose no TSE risk.

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:	Allow affected person to breathe fresh air. 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. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact:	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
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/effects: May cause an allergic skin reaction.

4.3 Most important symptoms and effects, both acute and delayed

No additional information available.

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 firefighting water from entering the environment.
Protection during firefighting:	Do not enter fire area without proper protective equipment, including respiratory protection.

Safety Data Sheet

SpermFilter[®] Ready-to-use gradient 80% / 45%

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Revision No.: 328/02
Page: 4/11

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. Notify authorities if liquid enters sewers or 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.

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 vapor.

Hygiene measures: Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Keep only in the original container away from direct (sun)light, in a cool and well-ventilated place. Do not freeze. Do not use after expiry date. After opening the container, the product can be used up to 7 days when sterile conditions are maintained and the products are stored at 2-8°C. Cannot be re-sterilized after opening.

Incompatible products: Strong bases. Strong acids.

Incompatible materials: Sources of ignition. Direct (sun)light.

Storage temperature: 2-8°C. Once opened 2-8°C.

7.3 Specific end use(s)

No additional information available.

Safety Data Sheet

SpermFilter® Ready-to-use gradient 80% / 45%

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Revision No.: 328/02
Page: 5/11

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

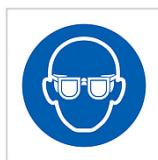
8.2.1. Appropriate engineering controls

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):



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).

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 specifications of regulation EU 2016/425 and the standard EN374.

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).

Thermal hazards:

No additional information available.

Safety Data Sheet

SpermFilter[®] Ready-to-use gradient 80% / 45%

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Revision No.: 328/02
Page: 6/11

Environmental exposure controls: Other information:
Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Reddish hazy solution
Odour:	Odourless
Odour threshold:	Not available
Melting point:	Not available
Freezing point:	Not available
Boiling point:	Not available
Flammability:	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:	7.2-7.9 (release criteria: 7.2-7.6)
Viscosity, kinematic:	Not available
Solubility:	Soluble in water
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:	45%: 1.0500-1.0700 g/ml 80%: 1.097-1.107 g/ml
Relative vapour density at 20 °C:	Not available
Particle characteristics:	Not applicable

9.2 Information on basic physical and chemical properties

9.2.1. Information with regard to physical hazard classes

No additional information available.

9.2.2. Other safety characteristics

No additional information available.

10 STABILITY AND REACTIVITY

10.1 Reactivity

No additional information available.

10.2 Chemical stability

Stable after transport (max. 5 days) at elevated temperature ($\leq 37^{\circ}\text{C}$).
Stable for 18 months from date of manufacture.

Safety Data Sheet

SpermFilter® Ready-to-use gradient 80% / 45%

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Revision No.: 328/02
Page: 7/11

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

Fume. Carbon monoxide. Carbon dioxide.

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
Additional information:	Based on available data, the classification criteria are not met
Skin corrosion/irritation:	Not classified
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:	Due to the potentially skin sensitizing nature of SIBO, this raw material was tested using an in vitro skin sensitization test in line with ISO 10993-10:2021. This has demonstrated that SIBO and consequently SpermFilter Stock Solution are classified as non-sensitizer.
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:	Extensive data on Human Sperm Survival Assays have demonstrated that the medium is not toxic.
STOT-single exposure:	Not classified
Additional information:	Based on available data, the classification criteria are not met
<i>Phenol red sodium salt (34487-61-1):</i>	
<i>STOT-single exposure:</i>	<i>_H_335_EU.: May cause respiratory irritation</i>
STOT-repeated exposure:	Not classified
Additional information:	Based on available data, the classification criteria are not met
Aspiration hazard:	Not classified
Additional information:	Based on available data, the classification criteria are not met

Safety Data Sheet

SpermFilter® Ready-to-use gradient 80% / 45%

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Revision No.: 328/02
Page: 8/11

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

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11.2.2. Other information

Potential adverse human health effects and symptoms:
Other information:

Based on available data, the classification criteria are not met
Human Serum Albumin: The plasma which is the source of the human serum albumin is tested for antibodies to HIV and HCV and non-reactive for HbsAg, HBV RNA, HCV RNA, HIV-1 RNA and syphilis. The albumin agrees with all the requirements set forth by the European and United States health authority regarding safety. Route of exposure: under normal conditions there is no exposure to the product.

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

SpermFilter® Ready-to-use
gradient 80% / 45%: Not established
Sodium Chloride (7647-14-5): Not established

12.3 Bioaccumulative potential

SpermFilter® Ready-to-use
gradient 80% / 45%: Not established
Sodium Chloride (7647-14-5): 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 Endocrine disrupting properties

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.

Safety Data Sheet

SpermFilter[®] Ready-to-use gradient 80% / 45%

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Revision No.: 328/02
Page: 9/11

12.7 Endocrine disrupting properties

Additional information: Avoid release to the environment.

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product/Packaging disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials: Avoid release to the environment.

14 TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

14.1 UN number

UN-No. (ADR) / (IMDG) / (IATA) / (ADN) / (RID): Not applicable

14.2 UN proper shipping name

Proper Shipping Name (ADR) / (IMDG) / (IATA) / (ADN) / (RID): Not applicable

14.3 Transport hazard class(es)

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

14.4 Packing group

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

Overland transport / Transport by sea / Air transport / Inland waterway transport / Rail transport: Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

Safety Data Sheet

SpermFilter® Ready-to-use gradient 80% / 45%

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Revision No.: 328/02
Page: 10/11

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

Netherlands

SZW-list of carcinogenic substances: None of the components are listed
SZW-list of mutagenic substances: None of the components are listed
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

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)

Denmark

Danish National Regulations: Young people below the age of 18 years are not allowed to use the product.
Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

Switzerland

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

Safety Data Sheet

SpermFilter® Ready-to-use gradient 80% / 45%

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Revision No.: 328/02
Page: 11/11

France: Occupational diseases

Code	Description
RG 31	Occupational diseases caused by aminoglycosides, including streptomycin, neomycin and their salts
RG 65	Ecematiform lesions of allergic mechanism
RG 66	Occupational rhinitis and asthma
RG 67	Nasal septum lesions caused by potassium chloride dust in potash mines and their dependencies
RG 78	Diseases caused by sodium chloride in salt mines and their dependencies

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

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-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Repr. 1A	Reproductive toxicity, Category 1A
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitization, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	_H_315_EU: Causes skin irritation
H317	_H_317_EU: May cause an allergic skin reaction
H319	_H_319_EU: Causes serious eye irritation
H334	_H_334_EU: May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	_H_335_EU: May cause respiratory irritation
H360	_H_360_EU: May damage fertility or the unborn child

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.