

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

1.1. Product identifier

Product form : Mixture
 Product name : Sil-Select Plus
 Sil-Select Plus with phenol red
 Sil-Select Plus with gentamicin
 Sil-Select Plus with phenol red and gentamicin

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

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

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ultrapure water	(CAS No) 7732-18-5 (EC no) 231-791-2	< 65	Not classified
Silica Basic Solution (SIBO)	-	45 (SIP Upper Layer) 90 (SIP Lower Layer) 80 (SIP 80%)	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (EC no) 231-598-3	0.1 - 1	Not classified
HEPES	(CAS No) 7365-45-9 (EC no) 230-907-9	0.1 - 1	Not classified
Human serum albumin	(CAS No) 70024-90-7	<0.25	Not classified
Sodium lactate	(CAS No) 867-56-1 (EC no) 212-762-3	0.1 - 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	< 0.1	Not classified

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Potassium Chloride	(CAS No) 7447-40-7 (EC no) 231-211-8	< 0.1	Not classified
Calcium chloride dihydrate	(CAS No) 10035-04-8	< 0.1	Eye Irrit. 2, H319
Sodium Dihydrogen Phosphate Dihydrate	(CAS No) 13472-35-0	< 0.1	Not classified
Magnesium Sulphate Heptahydrate	(CAS No) 10034-99-8	< 0.1	Not classified
Sodium Pyruvate	(CAS No) 113-24-6 (EC no) 204-024-4	< 0.1	Not classified
If applicable: Gentamicin sulfate	(CAS No) 1405-41-0	< 0.1	Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 1A, H360
If applicable: 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 R- and H-statements: see section 16

Comments:

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

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 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/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 the 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 .

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

Incompatible products : Strong bases. Strong acids.

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

Storage temperature : Products without gentamicin: 2-25°C. Products with gentamicin: 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

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 EU-directive 89/686/EEC and the standard EN374 derived from it.

Eye 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 using a mouth pipette.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : Bluish hazy solution. When product contains phenol red: reddish hazy solution

Odour : Odourless

Odour threshold : No data available

pH : 7.2-7.9 (release criteria: 7.2-7.6)

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

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Relative vapour density at 20 °C density	: No data available : For SIP 80%: 1.097-1.107 g/ml SIP Lower Layer: 1.1050-1.1150 g/ml
Solubility	: Highly soluble in water
Log Pow	: No data available
Viscosity	: SIP 80% and SIP Lower Layer: <1.65cP
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. 5 days) at elevated temperature ($\leq 37^{\circ}\text{C}$). 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 Extensive data on Sperm Survival tests have demonstrated that the medium is not toxic. Sil-Select Stock has been evaluated for its toxicity by an independent test laboratory using the AGAR diffusion test. The medium meets the requirements of the ISO 10993-5 guidelines.
Skin/ eye/mucosa irritation	: Not classified The product has been evaluated for its irritating potential by and independent test laboratory using the primary vaginal test-repeated exposure. The medium meets the requirements of te ISO 10993-10 guidelines.
Respiratory or skin sensitisation	: Not classified The product has been evaluated for its sensitizing potential by and independent test laboratory using the Kligman maximization test. The medium meets the requirements of te ISO 10993 guidelines.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified. The product has been evaluated for its biological reaction by an independent test laboratory using the systemic injection test (single dose). The medium meets the requirements of the ISO 10993 guidelines.
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

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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. Other adverse effects

Additional information : 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)

ADR

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

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

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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

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.

Full text of R-, H- and EUH-statements:

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
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

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