

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

1.1. Product identifier

Product form : Mixture
Product name : SpermFreeze SSP

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 : Medium for freezing human sperm

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 | 70 - 90 | Not classified |
| Glycerol | (CAS No) 56-81-5 (EC no) 200-289-5 | 20 - 30 | Not classified |
| Sucrose | (CAS No) 57-50-1 (EC no) 200-334-9 | 1 - 5 | Not classified |
| Glycine | (CAS No) 56-40-6 (EC no) 200-272-2 | ≤ 1 | Not classified |
| Sodium Chloride | (CAS No) 7647-14-5 (EC no) 231-598-3 | < 1 | Not classified |
| HEPES | (CAS No) 7365-45-9 (EC no) 230-907-9 | < 1 | Not classified |
| Human Serum Albumin | (CAS No) 70024-90-7 | < 1 | Not classified |
| Sodium Hydrogen Carbonate | (CAS No) 144-55-8 (EC no) 205-633-8 | < 1 | Not classified |
| Glucose Monohydrate | (CAS No) 14431-43-7 | < 1 | Not classified |
| Calcium Lactate Pentahydrate | (CAS No) 5743-47-5 | < 1 | Not classified |
| Potassium Chloride | (CAS No) 7447-40-7 (EC no) 231-211-8 | < 1 | Not classified |
| Magnesium Sulphate Heptahydrate | (CAS No) 10034-99-8 | < 1 | Not classified |
| Sodium Dihydrogen Phosphate Dihydrate | (CAS No) 13472-35-0 | < 1 | Not classified |

Full text of H-phrases: see section 16

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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 : 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.

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.

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

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.

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. After opening the container, the product can be safely used up to 7 days when sterile conditions are maintained and the products are stored at 2-8°C. Do not freeze. Do not use after expiry date. Content cannot be re-sterilized.

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.

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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 specifications of regulation EU 2016/425 and the standard EN374. |
| 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 | : Colourless. |
| Odour | : Odourless |
| Odour threshold | : No data available |
| pH | : 7.20 – 7.90 |
| 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 |
| 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. 5 days) at elevated temperature ($\leq 37^{\circ}\text{C}$). Stable for 18 months after date of manufacture.

10.3. Possibility of hazardous reactions

Not established.

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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 (oral, dermal, inhalation) | : Not classified Extensive data on Sperm Survival Tests have demonstrated that the medium is not toxic. |
| Skin corrosion/irritation | : Based on available data, the classification criteria are not met. |
| Serious eye damage/irritation | : Based on available data, the classification criteria are not met. |
| Respiratory or skin sensitisation | : Based on available data, the classification criteria are not met. |
| Germ cell mutagenicity | : Based on available data, the classification criteria are not met. |
| Carcinogenicity | : Based on available data, the classification criteria are not met. |
| Reproductive toxicity | : Based on available data, the classification criteria are not met. |
| Specific target organ toxicity (single exposure) | : Based on available data, the classification criteria are not met. |
| Specific target organ toxicity (repeated exposure) | : Based on available data, the classification criteria are not met. |
| Aspiration hazard | : Based on available data, the classification criteria are not met. |
| Potential adverse human health effects and symptoms | : Based on available data, the classification criteria are not met. |
| Other information | : 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: In normal use, there is no contact between SpermFreeze and the patient. |

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. |
|-------------------------------|------------------|

12.3. Bioaccumulative potential

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| | |
|---------------------------|------------------|
| Bioaccumulative potential | 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. 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

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

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| | |
|-----------------------------|------------------|
| 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)

| | |
|-----------------------------------|------------------|
| 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

| | |
|---------------------------|---------------------|
| 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. 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

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

15.1.2. National regulations

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-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

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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.

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