

MATERIAL SAFETY DATA SHEET

FertiPro N.V.- Belgium

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name : SpermFreeze
Product use : Medium for freezing human semen (for professional use only)
Distributor : FertiPro N.V.
Industriepark Noord 32
B-8730 Beernem
Belgium
For emergency information : 32 50 79 18 05

2. HAZARD IDENTIFICATION

SpermFreeze medium is not considered as a dangerous substance according to Directive 67/548/EEC and Directive 1999/45/EC.

Potential Acute Health Effects : May be harmful by ingestion
May cause skin or eye irritation
May be irritating to mucous membranes and upper respiratory tract
Potential Chronic Health Effects : Not available

3. COMPOSITION / INFORMATION ON THE COMPONENTS

Product components:	Component	CAS-code	Approx. %
	Water	7732-18-5	85%
	Glycerine	56-81-5	15%
	NaCl	7647-14-5	< 1%
	KCl	7447-40-7	< 1%
	MgSO ₄ .7H ₂ O	10034-99-8	< 1%
	NaH ₂ PO ₄ .2H ₂ O	13472-35-0	< 1%
	Sucrose	57-50-1	< 2%
	Glycine	56-40-6	< 1%
	Glucose monohydrate	14431-43-7	< 1%
	HEPES	7365-45-9	< 2%
	NaHCO ₃	144-55-8	< 1%
	Ca-lactate.5H ₂ O	5743-47-5	< 1%
	Human serum albumin	70024-90-7	0.4%

SpermFreeze does 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.

4. FIRST AID MEASURES

Inhalation : Not a likely source of exposure
Eyes : Flush with copious amounts of water for at least 15 minutes. Insure adequate flushing by separating the eyelids with fingers

Skin : Wash after each contact
Ingestion : wash out mouth with water (see doctor when swallowing)
Obtain medical attention if any discomfort should occur.

5. FIRE FIGHTING MEASURES

Extinguishing media : Not applicable
Special exposure hazards : Not applicable
Special fire fighting procedure : Not applicable
Unusual fire and explosion hazards : Not applicable

6. ACCIDENTAL RELEASE MEASURES

Personal precautions : Wear chemical safety goggles. Wear rubber gloves.
avoid contact with skin, eyes and clothing
Environmental precautions : Not applicable
Methods for cleaning up : Rinse spill area with water. Dispose with laboratory waste

7. HANDLING AND STORAGE

Handling : See heading 8
Storage : Store at 2-8°C. Do not freeze before use. Keep away
from sunlight. After opening the container, do not use the
product longer than 7 days. Do not use after expiry date
Specific use : See instructions for use delivered with the device

8. EXPOSURE CONTROL / PERSONAL PROTECTION

Exposure limit values : Not applicable
(Occupational) exposure controls : Wear chemical safety goggles. Wear rubber gloves.
Avoid contact with skin, eyes and clothing. Avoid
inhalation. Avoid mouth pipetting
Environmental exposure controls : Not applicable

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and odour : White/yellow transparent liquid, odourless
pH : 7.30-7.60
Boiling point : Not available
Flash point : Not available
Flammability : Not available
Explosive properties : Not available
Oxidising properties : Not available
Vapour pressure : Not available
Relative density : Not available
Solubility : Highly soluble in water
Solubility in water : Complete
Partition coefficient : Not applicable
Viscosity : Not available
Vapour density : Not available
Evaporation rate : Not available

10. STABILITY AND REACTIVITY

Stability : Stable
Conditions to avoid : None known

Materials to avoid : None known
Hazardous decomposition products : None

11. TOXICOLOGICAL INFORMATION

Human serum albumin : The plasma manufactured by Baxter and Talecris (Grifols) which is the source for the human serum albumin is tested for anti-HIV 1, anti-HIV 2, anti-HCV and HbsAG. The albumin agrees with all the requirements set forth by the European and United States health authority regarding safety

Cytotoxicity : Extensive data on Mouse Embryo Assays have demonstrated that the medium is not toxic

Routes of exposure : In normal use there is no contact between SpermFreeze and the patient

12. ECOLOGICAL INFORMATION

Ecotoxicity : No known ecological damage
Mobility : Not available
Persistence and degradability : Not available
Bioaccumulative potential : Not available

13. DISPOSAL

Dispose with laboratory waste.

14. TRANSPORT INFORMATION

Not classified as Hazardous for Transport.

15. REGULATORY INFORMATION

This product does not contain any ingredients which have been determined to be health hazards pursuant to U.S. OSHA regulations, and which comprise 1% or more (0.1% for carcinogens) of the mixture.

Information shown on the labels : Name of the medium. Volume. Reference number. Lot number. Expiry date. Temperature limitation: 2-8°C. Keep away from sunlight. Read instructions for use. Sterilized by aseptic filtration. Name and address of manufacturer. Label version number.

16. OTHER INFORMATION

The information contained herein is furnished without warranty of any kind. Users should consider these data only as a supplement to other information gathered by them and must take independent determinations of the suitability and completeness of information from all other sources to assure proper use and disposal of these materials and the safety and health of employees and customers. FertiPro N.V. shall not be held liable for any damage resulting from handling or from contact with its products.