

MATERIAL SAFETY DATA SHEET

FertiPro N.V.- Belgium

1. IDENTIFICATION OF THE SUBSTANCES/PREPARATION AND OF THE COMPANY

Product name	:	FertiCult Flushing medium
Product use	:	Cell culture medium for washing of ova, spermatozoa, human embryos, sperm injection in ICSI, sperm swim-up, embryo transfer, intra-uterine insemination, production of density gradients (for professional use only)
Manufacturer	:	FertiPro N.V. Industriepark Noord 32 B-8730 Beernem Belgium
For emergency information	:	32 50 79 18 05 (only available during European office hours)

2. HAZARD IDENTIFICATION

FertiCult Flushing 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	> 90%
	NaCl	7647-14-5	< 1%
	KCl	7447-40-7	< 1%
	CaCl ₂ ·2H ₂ O	10035-04-8	< 1%
	NaH ₂ PO ₄ ·2H ₂ O	13472-35-0	< 1%
	MgSO ₄ ·7H ₂ O	10034-99-8	< 1%
	Na-pyruvate	113-24-6	< 1%
	Glucose monohydrate	14431-43-7	< 1%
	Na-lactate	867-56-1	< 1%
	NaHCO ₃	144-55-8	< 1%
	HSA	70024-90-7	0.4%
	HEPES	7365-45-9	< 2%

FertiCult Flushing medium 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
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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 2-25°C (once opened, store at 2-8°C). Do not freeze before use. Keep away from sunlight. After opening the container, the product can be used safely up to 7 days after opening when sterile conditions are maintained. 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	:	7.30-7.90
Boiling point	:	Not available
Flash point	:	Not available
Flammability	:	Does not contain flammable substances
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 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
Cytotoxicity	:	Extensive data on Mouse Embryo Assays have demonstrated that the medium is not toxic
Sensitization	:	FertiCult Flushing medium with phenol red and gentamicin has been evaluated for its sensitizing potential by an independent test laboratory using the Kligman maximization test. The medium meets the requirements of the ISO 10993-10 guidelines
Irritation	:	FertiCult Flushing medium with phenol red and gentamicin has been evaluated for its irritating potential by an independent test laboratory using the direct intracutaneous injection test. The medium meets the requirements of the ISO 10993-10 guidelines
Routes of exposure	:	With embryo transfer and intra-uterine insemination, the medium comes into contact with the uterus mucosal membranes

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Dispose with laboratory waste.

14. TRANSPORT INFORMATION

Not classified as Hazardous for Transport.

15. REGULATORY INFORMATIONS

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: 2-25°C. Keep away from sunlight. Read instructions for use. Sterilized by aseptic filtration. Name and address of manufacturer. Label version number.
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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.