

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

#### 1.1. Product identifier

Product form : Mixture  
 Product name : FertiCult Aspiration medium

#### 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 : Cell culture medium for human oocyte aspiration and flushing of the ovarian follicles during oocyte pick-up

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

FertiPro nv  
 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. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ultrapure water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	90 – 99	Not classified

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sodium heparin	(CAS-No.) 9041-08-1	<0.1	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
Sodium lactate	Not determined	0.1 – 1	Not classified
Glucose monohydrate	(CAS-No.) 14431-43-7	0.1 – 1	Not classified
Sodium Hydrogen Carbonate	(CAS-No.) 144-55-8 (EC-No.) 205-633-8	0.1 – 1	Not classified
Calcium chloride dihydrate	(CAS-No.) 10035-04-8	< 0.1	Eye Irrit. 2, H319
Magnesium Sulphate Heptahydrate	(CAS-No.) 10034-99-8	< 0.1	Not classified
Potassium Chloride	(CAS-No.) 7447-40-7 (EC-No.) 231-211-8	< 0.1	Not classified
Sodium Pyruvate	(CAS-No.) 113-24-6 (EC-No.) 204-024-4	< 0.1	Not classified
Sodium Dihydrogen Phosphate Dihydrate	(CAS-No.) 13472-35-0	< 0.1	Not classified

Full text of H-statements: see section 16

Comments

: FertiCult™ Aspiration medium contains heparin which is derived from porcine intestinal mucosa.

## 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 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

: 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.

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### 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. Store away from other materials.

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

Incompatible products : Strong bases. Strong acids.

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

Storage temperature : 2 – 25 °C (once opened, store at 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 control:

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.

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### 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/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).

### 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 liquid using a mouth pipette.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: white to slightly yellow.
Odour	: odourless.
Odour threshold	: No data available
pH	: 7.3 – 7.9 (@ 25°C, under air)
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	: highly soluble in water.
Partition coefficient n-octanol/water (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

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### 10.2. Chemical stability

Stable after transport (max. 5 days) at elevated (<37°C) temperature. 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

fume. Carbon monoxide. Carbon dioxide.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
	Extensive data on Mouse Embryo Assays have demonstrated that the medium is not toxic
Skin corrosion/irritation	: The medium meets the requirements of the ISO 10993-10 guideline. This was determined by independent test laboratory using the direct intracutaneous injection test pH: 7.3 – 7.9 (@ 25°C, under air)
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified
	pH: 7.3 – 7.9 (@ 25°C, under air)
Additional information	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: The medium meets the requirements of the ISO 10993-10 guideline. This was determined by an independent test laboratory using the Kligman maximization test.
Additional information	: Based on available data, the classification criteria are not met
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	: Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
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
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.
Other information	: Route of exposure: with oocyte pick-up and follicular flushing, the medium comes into contact with ovarian follicles.

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### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : No known ecological damage caused by this product.  
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

FertiCult Aspiration medium	
Persistence and degradability	Not established.

#### Sodium Chloride (7647-14-5)

Persistence and degradability	Not established.
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#### 12.3. Bioaccumulative potential

FertiCult Aspiration medium	
Bioaccumulative potential	Not established.

#### 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

Product/Packaging 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

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

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### 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)

<b>ADR</b>	
Transport hazard class(es) (ADR)	: Not applicable
<b>IMDG</b>	
Transport hazard class(es) (IMDG)	: Not applicable
<b>IATA</b>	
Transport hazard class(es) (IATA)	: Not applicable
<b>ADN</b>	
Transport hazard class(es) (ADN)	: Not applicable
<b>RID</b>	
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 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.

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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-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

### 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.

#### Classification according to Regulation (EC) No. 1272/2008 [CLP]:

Not classified	
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#### Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H319	_H_319_EU: Causes serious eye irritation

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.