

SECTION 1: Identification of the substance/mixture and of the company/undertaking
1.1. Product identifier

Product form : Mixture
 Product name : FertiCult IVF medium
 FertiCult IVF medium with phenol red
 FertiCult IVF medium 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 : Cell culture medium for washing/holding of human oocytes and fertilization by IVF/ICSI (until 2PN)

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

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

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 | ≥ 99 | Not classified |
| Sodium chloride | (CAS No) 7647-14-5 (EC No) 231-598-3 | < 1 | Not classified |
| Human serum albumin | (CAS No) 70024-90-7 | < 1 | Not classified |
| Sodium lactate | (CAS No) Not determined (EC No) 212-762-3 | < 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 |
| Potassium chloride | (CAS No) 7447-40-7 (EC No) 231-211-8 | < 0.1 | Not classified |

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| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---------------------------------------|--|-------|---|
| 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 | (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-phrases: see section 16

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 as soon as possible. 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. |
|-------------------------------|--|

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7.2. Conditions for safe storage, including any incompatibilities

| | |
|------------------------|---|
| Storage conditions | : Keep only in the original container away from direct (sun)light. Do not freeze. Do not use after expiry date. After opening the container, the product can be used up to 7 days when sterile conditions are maintained and the products are stored at 2-8°C. Cannot be re-sterilized after opening. |
| Incompatible products | : Strong bases. Strong acids. |
| Incompatible materials | : Sources of ignition. Direct (sun)light. |
| Storage temperature | : When the medium contains gentamicin: 2-8 °C. When the medium does not contain gentamicin: 2-25°C Once opened: 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

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

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).

8.2.2.2. Skin protection

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.

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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8.2.2.3. Respiratory protection

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).

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

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/yellow or reddish transparent fluid. |
| Odour | : Characteristic. |
| Odour threshold | : Not available |
| Melting point | : Not available |
| Freezing point | : Not available |
| Boiling point | : Not available |
| Flammability | : Non flammable |
| Explosive limits | : Not available |
| Lower explosion limit | : Not available |
| Upper explosion limit | : Not available |
| Flash point | : Not available |
| Auto-ignition temperature | : Not available |
| Decomposition temperature | : Not available |
| pH | : 7.20- 7.50 (37°C – 6% CO ₂) |
| Viscosity, kinematic | : Not available |
| Solubility | : Soluble in water. |
| Partition coefficient n-octanol/water (Log Kow) | : Not available |
| Vapour pressure | : Not available |
| Vapour pressure at 50 °C | : Not available |
| Density | : Not available |
| Relative density | : Not available |
| Relative vapour density at 20 °C | : Not available |
| Particle characteristics | : Not applicable |

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable after transport (max. 5 days) at elevated temperature ($\leq 37^{\circ}\text{C}$). Stable for 12 months from date of manufacture.

10.2. Chemical stability

Not established.

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.

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10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide. Fume.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

| | |
|---|---|
| Acute toxicity (oral, dermal, inhalation) | : Not classified Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic. |
| Skin corrosion/irritation | : Not classified pH: 7.2-7.5 (37°C – 6% CO ₂) |
| Additional information | : Based on available data, the classification criteria are not met |
| Serious eye damage/irritation | : Not classified pH: 7.2- 7.5 (37°C – 6% CO ₂) |
| Additional information | : Based on available data, the classification criteria are not met |
| Respiratory or skin sensitisation | : Not classified |
| 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 |

Phenol red sodium salt (34487-61-1)

| | |
|------------------------|--|
| STOT-single exposure | _H_335_EU. |
| 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 |

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information available

11.2.2. Other information

| | |
|---|--|
| Potential adverse human health effects and symptoms | : Based on available data, the classification criteria are not met |
| Other information | : Human Albumin Solution: 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, Under normal conditions there is no exposure to the product. |

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.

Sodium Chloride (7647-14-5)

Persistence and degradability Not established.

12.3. Bioaccumulative potential

FertiCult IVF medium (with phenol red (and gentamicin))

Bioaccumulative potential Not established.

Sodium Chloride (7647-14-5)

Bioaccumulative potential Not established.

12.4. Mobility in soil

No additional information available

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12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

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

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

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

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

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14.7. Maritime transport in bulk according to IMO instruments

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

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

| France | |
|-----------------------|---|
| Occupational diseases | |
| Code | Description |
| RG 31 | Occupational diseases caused by aminoglycosides, including streptomycin, neomycin and their salts |
| RG 67 | Nasal septum lesions caused by potassium chloride dust in potash mines and their dependencies |
| RG 78 | Diseases caused by sodium chloride in salt mines and their dependencies |

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 -

: None of the components are listed

Breastfeeding

NON-exhaustive list of reproductive toxins - Fertility

: None of the components are listed

NON-exhaustive list of reproductive toxins -

: None of the components are listed

Development

Switzerland

Storage class (LK)

: LK 10/12 - Liquids

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 H- and EUH-statements:

| | |
|---------------|---|
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| Repr. 1A | Reproductive toxicity, Category 1A |
| Resp. Sens. 1 | Respiratory sensitisation, Category 1 |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |

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| | |
|--------------|--|
| Skin Sens. 1 | Skin sensitisation, Category 1 |
| STOT SE 3 | Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation |
| H315 | _H_315_EU : Causes skin irritation |
| H317 | _H_317_EU : May cause an allergic skin reaction |
| H319 | _H_319_EU : Causes serious eye irritation |
| H334 | _H_334_EU : May cause allergy or asthma symptoms or breathing difficulties if inhaled |
| H335 | _H_335_EU : May cause respiratory irritation |
| H360 | _H_360_EU : 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