

MEDIA COOLING KIT (38070) and MEDIA WARMING KIT (38080), MEDIA WARMING KIT FOR OPEN SYSTEM (38090)

SECTION 1. Identification of the substance / mixture and of the company

1.1. Product identifiers

Product form	:	Mixture
Product name	:	MEDIA COOLING KIT - MEDIA WARMING KIT - MEDIA WARMING KIT FOR OS
Product code	:	38070 – 38080 - 38090

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	:	Cryopreservation medium for human oocytes and embryos. Only for professional use.
Unidentified uses	:	Uses not included in the identified uses.

1.3. Details of the supplier

Company	:	Vecmedical Spain, S.L. Pol. Ind. Can Milans, nave 9 08110 Montcada i Reixac Barcelona – Spain
Telephone	:	+34 935725015
Fax	:	+34 935725013
E-mail address	:	vecmedical@vecmedical.com

1.4. Emergency telephone number

Emergency phone	:	+34 935725015 (Vecmedical España)
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SECTION 2. Hazards identification

2.1. Clasification of the substance or mixture

Classification according to European Directive 93/42/EC
Medical device, Class III according to Rule 13.

Classification according to Regulation (EC) No. 1272/2008
No classification.

2.2. Label elements

Labels according to standard UNE-EN ISO 15223-1:2022

Symbol

Description



Symbol "DO NOT REUSE"



Symbol "DO NOT REESTERILIZE"

MEDIA COOLING KIT (38070) and MEDIA WARMING KIT (38080), MEDIA WARMING KIT FOR OPEN SYSTEM (38090)



Symbol "USE-BY DATE"



Symbol "BATCH CODE"



Symbol "Sterilized using aseptic processing techniques"



Symbol "A SINGLE STERILE BARRIER SYSTEM"



Symbol "CATALOG CODE"



Symbol "CAUTION"



Symbol "CONSULT INSTRUCTIONS FOR USE"



Symbol "TEMPERATURE LIMIT"



Symbol "KEEP OUT OF THE SUNLIGHT".



Symbol "MANUFACTURER".



Symbol "DATE OF MANUFACTURE".



Symbol "DO NOT USE IF PACKAGING IS DAMAGED".



Symbol "MEDICAL DEVICE".



Symbol "UNIQUE PRODUCT IDENTIFIER".

2.3. Other hazards No additional information available.

SECTION 3. Composition/information on ingredients

3.1. Substance

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No applicable.

3.2. Mixture

Reference	Substance
38059	SAFESPEED MEDIA BUFFER SOLUTION
38070 MEDIA COOLING KIT	
38060	SAFESPEED MEDIA WASHING SOLUTION
38061	SAFESPEED MEDIA EQUILIBRATION SOLUTION
38062	SAFESPEED MEDIA VITRIFICATION SOLUTION
38080 MEDIA WARMING KIT	
38060	SAFESPEED MEDIA WASHING SOLUTION
38063	SAFESPEED MEDIA THAWING SOLUTION
38064	SAFESPEED MEDIA DILUENT SOLUTION
38090 MEDIA WARMING KIT FOR OS (OPEN SYSTEM)	
38060	SAFESPEED MEDIA WASHING SOLUTION
38063 (4x)	SAFESPEED MEDIA THAWING SOLUTION
38064	SAFESPEED MEDIA DILUENT SOLUTION

SAFESPEED MEDIA BUFFER SOLUTION – 38059

CODE Vecmedical	SOLUTION NAME	N° CAS	CONCENTRATION	CLASSIFICATION ACCORDING TO REGULATION (EC) 1272/2008	SUPPLIER REFERENCE	MANUFACTURER
03527	PHOSPHATE BUFFERED SALINE		90 – 100%	Not a hazardous substance or mixture.	PBS D8662- 500ML	SIGMA
03528	HYDROXYPROPYL CELLULOSE	9004-64-2	< 0,1%	Not a hazardous substance or mixture.	HPC 435007- 100G	ALDRICH
03534	SODIUM PYRUVATE	113-24-6	< 0,1%	Not a hazardous substance or mixture.	Na-Pyr P4562- 5G	SIGMA
03531	SUCROSE	57-50-1	< 0,5%	Not a hazardous substance or mixture.	Sacarosa 84097-250G	SIGMA

SAFESPEED MEDIA WASHING SOLUTION – 38060

CODE Vecmedical	SOLUTION NAME	N° CAS	CONCENTRATION	CLASSIFICATION ACCORDING TO REGULATION (EC) 1272/2008	SUPPLIER REFERENCE	MANUFACTURER
38059	BUFFER SOLUTION		90 – 100%			
03535	PHENOL RED	143-74-8	< 0,1%	Not a hazardous substance or mixture	PHENOL RED P3532-5G	SIGMA- ALDRICH
03549	SODIUM HYDROXIDE SOLUTION	1310-73-2	< 0,1%		NaOH S2770- 100ML	SIGMA

SAFESPEED MEDIA EQUILIBRATION SOLUTION – 38061

CODE Vecmedical	SOLUTION NAME	N° CAS	CONCENTRATION	CLASSIFICATION ACCORDING TO REGULATION (EC) 1272/2008	SUPPLIER REFERENCE	MANUFACTURER
38059	BUFFER SOLUTION		90 – 100%			
03529	ETHYLENGLYCOL	107-21-1	7.5%		EG 03750- 250ML	HONEYWELL

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03530	DIMETHYLSULFOXIDE	67-68-5	7.5%	Not a hazardous substance or mixture	DMSO D2650-100ML	SIGMA
03535	PHENOL RED	143-74-8	< 0,1%	Not a hazardous substance or mixture	PHENOL RED P3532-5G	SIGMA-ALDRICH
03550	HYDROCHLORIC ACID SOLUTION	7647-01-0	< 0,1%		HCl H9892-100ML	SIGMA

SAFESPEED MEDIA VITRIFICATION SOLUTION – 38062

CODE Vecmedical	SOLUTION NAME	Nº CAS	CONCENTRATION	CLASSIFICATION ACCORDING TO REGULATION (EC) 1272/2008	SUPPLIER REFERENCE	MANUFACTURER
38059	BUFFER SOLUTION		90 – 100%			
03529	ETHYLENGLYCOL	107-21-1	15%		EG 03750-250ML	HONEYWELL
03530	DIMETHYLSULFOXIDE	67-68-5	15%	Not a hazardous substance or mixture	DMSO D2650-100ML	SIGMA
03531	SUCROSE	57-50-1	0,5M	Not a hazardous substance or mixture	Sacarosa 84097-250G	SIGMA
03535	PHENOL RED	143-74-8	< 0,1%	Not a hazardous substance or mixture	PHENOL RED P3532-5G	SIGMA-ALDRICH
03550	HYDROCHLORIC ACID SOLUTION	7647-01-0	< 0,1%		HCl H9892-100ML	SIGMA

SAFESPEED MEDIA THAWING SOLUTION – 38063

CODE Vecmedical	SOLUTION NAME	Nº CAS	CONCENTRATION	CLASSIFICATION ACCORDING TO REGULATION (EC) 1272/2008	SUPPLIER REFERENCE	MANUFACTURER
38059	BUFFER SOLUTION		90 – 100%			
03531	SUCROSE	57-50-1	1M	Not a hazardous substance or mixture	Sacarosa 84097-250G	SIGMA
03535	PHENOL RED	143-74-8	< 0,1%	Not a hazardous substance or mixture	PHENOL RED P3532-5G	SIGMA-ALDRICH
03549	SODIUM HYDROXIDE SOLUTION	1310-73-2	< 0,1%		NaOH S2770-100ML	SIGMA

SAFESPEED MEDIA DILUENT SOLUTION – 38064

CODE Vecmedical	SOLUTION NAME	Nº CAS	CONCENTRATION	CLASSIFICATION ACCORDING TO REGULATION (EC) 1272/2008	SUPPLIER REFERENCE	MANUFACTURER
38059	BUFFER SOLUTION		90 – 100%			
03531	SUCROSE	57-50-1	0,5M	Not a hazardous substance or mixture	Sacarosa 84097-250G	SIGMA
03535	PHENOL RED	143-74-8	< 0,1%	Not a hazardous substance or mixture	PHENOL RED P3532-5G	SIGMA-ALDRICH
03549	SODIUM HYDROXIDE SOLUTION	1310-73-2	< 0,1%		NaOH S2770-100ML	SIGMA

SECTION 4: First aid measures

4.1. Description of first aid measures

If inhaled

No specific treatment is necessary, as this material is unlikely to be hazardous by inhalation.

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In case of skin contact

Not toxic. Wash off with soap and plenty of water.

In case of eyes contacts

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2. Most important symptoms and effects, both acute and delayed

It is not expected to present a significant hazard under the intended 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

The substance/mixture will not burn. In case of fire in the vicinity, use an appropriate extinguishing agent.

Unsuitable extinguishing media

No additional information available.

5.2. Special hazards arising from the substance or mixture

No additional information available.

5.3. Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. Accidental release measure

6.1. Personal precautions, protective equipment and emergency procedures

No special precautions or procedures required.
For personal protection see section 8.

6.2. Environmental precautions

No special environmental precautions required. Still, it is suggested its disposal by a waste manager.

6.3. Methods and materials for containment and cleaning up

Keep in suitable, closed containers for disposal. Maintain proper workspace cleanliness.

6.4. Reference to other sections

For disposal see section 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

The cold chain must be ensured, during handling and storage. The required temperature is 2-8°C.

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7.2. Conditions for safe storage, including any incompatibilities

Store in original container at 2-8°C protected from light. Do not use media that have not been store under these conditions. When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Do not freeze before use.

To avoid contamination problems, aseptic handling techniques should be used.

Do not use product if expire data has been exceeded.

Do not re-sterilise.

Do not re-use. This product is for a single use and not to be reused due to the risk of contamination.

7.3. Specific end uses

Please refer to the instructions for use delivered with the product.

SECTION 8. Exposure controls / personal protection

8.1. Control parameters

No additional information available.

8.2. Exposure controls

Appropriate engineering controls

The general instructions of the company/facility where it is handled must be followed.

Personal protective equipment

No special protection is required for the handling of this product.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance	Form: Liquid Color: yellow / pink
b) Odour	No data available
c) Odour threshold	No data available
d) pH	7.2-7.6
e) Melting point / freezing point	No data available
f) Initial boiling point and boiling range	No data available
g) Flash point	No data available
h) Evaporation rate	No data available
i) Flammability (solid, gas)	Non-flammable
j) Upper / lower flammability or explosive limits	No data available
k) Vapour pressure	No data available
l) Vapour density	No data available
m) Relative density	No data available
n) Water solubility	Highly soluble in water
o) Partition coefficient: n-octanal/water	No data available

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|------------------------------|----------------------------|
| p) Auto-ignition temperature | No data available |
| q) Decomposition temperature | Out of storage range 2-8°C |
| r) Viscosity | No data available |
| s) Explosive properties | No data available |
| t) Oxidizing properties | No data available |

9.2. Other safety information

No data available.

SECTION 10. Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended storage conditions (2-8°C).

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Other decomposition products – No data available.

Hazardous decomposition products formed under fire conditions. – Carbon oxides.

10.7. Expiration Date

12 months after the manufacturing date.

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

No data available. Extensive data from Mouse Embryo Assays have shown the medium to be non-toxic.

Skin corrosión / irritation

No data available.

Serious eye damage / eye irritation

No data available.

Respiratory or skin sensitisation

No data available.

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Germ cell mutagenicity

No data available.

Carcinogenicity

No data available.

Reproductive toxicity

No data available.

Specific target organ toxicity - single exposure

No data available.

Specific target organ toxicity - repeated exposure

No data available.

Aspiration hazard

No data available.

Additional Information

Currently, clinical research literature indicates that the long-term effects of vitrification on oocytes and embryos, and on newborn infants born after cryopreservation remain unknown.

SECTION 12. Ecological information

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No additional information available.

12.6. Other adverse effects

No data available.

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Product

Discard the product as residual and non-reusable solutions.
No special precautions required. Still, it is suggested its disposal by a waste manager.

Packaging

Discard the containers and packaging as indicated to containers with solutions inside.

SECTION 14. Transport information

MEDIA COOLING KIT (38070) and MEDIA WARMING KIT (38080), MEDIA WARMING KIT FOR OPEN SYSTEM (38090)

14.1. UN number

ADR/RID: - IMDG: - IATA: -

14.2. UN proper shipping name

ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

14.3. Transport Hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4. Packaging group

ADR/RID: - IMDG: - IATA: -

14.5. Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6. Special precautions for user

Maintain the cold chain (2-8°C). It is suggested to make the transport with dry ice and porex box. In addition, use labels identifying cold, and fragile shipment.

SECTION 15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

European Directive 93/42 and Regulation (EC) 2017/745 on medical devices.

COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

15.2. Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16. Other information

The information in this document is based on the present state of our knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It does not represent any guarantee of the properties of the product