

HV-Oil

High viscosity Mineral oil (Paraffin oil).

Product No.:

506050

Indications for use

HV-Oil is a high viscosity mineral oil (d=0.86-0.88g/ml) a pre-washed with ultra pure water for use in In Vitro Fertilization (IVF), Intracytoplasmic Sperm Injection (ICSI) and assisted reproductive technologies (ART).

The oil permits small volumes of medium to be used for fertilization and embryo culture / handling. The oil overlay prevents media evaporation, which would result in increased osmolality, and to avoid fluctuations in the pH and the temperature.

For professional use only.

Technical Support

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Device Description

50 ml glass bottles, single packed, provided sterile. The HV-Oil is a pharmaceutical grade light mineral oil*), pre-washed and sterile filtered light paraffin oil.

*) Liquid paraffin oil is a mineral oil and is a by-product of crude oil distillation.

Quality Control Specifications

Density: 0.86-0.88g/ml

Viscosity: 95-140cP at 30 °C

Endotoxin : < 0.1EU/ml USP <85>

Peroxide Value (POV): < 0.1mEq/kg

Sterility : No growth (Ph. Eur. 2.6.1, USP<71>)

1-Cell Mouse Embryo Assay: ≥ 80% blastocysts

embryos

developed to expanded blastocyst at 120 hours

The results of each batch are stated on Certificate of Analysis, which is available at www.artsmediadenmark.com

Storage

Keep away from sunlight at 2-8° C in original container. Do not freeze. The products can be used up to 1 month after opening, when sterile conditions are maintained and the products are stored at room temperature. Stable after transport (max. 5 days) at elevated temperature (≤ 37 °C).

Warnings

- Do not use after expiry date
- Do not use if the product is cloudy or shows any evidence of microbial contamination.
- Do not use if seal of the container is damaged or open upon delivery.
- Do not use product that shows any evidence of particulate matter or has changed color.
- Do not re-sterilize after opening.
- Discard media that has been warmed and not used.
- Discard in accordance with local regulations for disposal of medical devices.

Precautions













- All human organic samples should be handled as if capable of transmitting HIV or hepatitis.
- Oil use should be conducted using aseptic techniques.
- Always wear protective clothing when handling samples.

Instruction for use

HV-Oil is pre-washed and ready to use. The oil should be pre-warmed prior to use.

To maintain pH, temperature, and osmolality, make sure that the medium is completely covered with oil.

The oil should be used according to the established procedures and protocols optimized for the individual clinic.

 5.7.7	Medical device
 5.2.8	Do not use if package is damaged
 5.4.3	Consult instructions for use or consult electronic instructions for use
 5.4.4	Caution
 5.2.11	Single sterile barrier system
 5.2.2	Sterilized using aseptic processing techniques (filtration)
 5.3.2	Keep away from sunlight
 5.3.7	Storage temperature limits 2-8°C
Rx only	Caution U.S Federal law restricts this device to sale by or on the order of a physician. (21CFR801.109)
 5.1.1	Manufacturer
 5.1.4	Use-by date: Year-Month-Day
 5.1.6	Catalog Number
 5.1.5	Batch code
*Symbol Reference – ISO 15223-1:2021, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	

Glossary of Symbols*