

GM501 Mineral Oil

Material included in the package:

- 100 ml GM501 Mineral Oil
- 500 ml GM501 Mineral Oil

Material not included in the package:

- Incubator (at 37°C)
- Petri dishes
- LAF-bench (ISO Class 5 Environment)
- Microscope
- Test tubes
- Cell culture media

Composition:

Mineral Oil

- CAS code: 8042-47-5
- EP Monograph: 0240

Product code:

- 4 MO 0100
- 4 MO 0500

General Information:

- GM501 Mineral Oil is pre-washed, ready-to-use, light mineral oil (d=0.83 - 0.86 g/ml), for use with culture media in IVF, ICSI and related assisted reproduction procedures. The oil is pre-washed twice with ultrapure water and may be used to coat culture dishes and flasks and as an overlay for media droplets, thereby preventing evaporation and stabilizing pH and temperature.

Indications for Use:

- GM501 Mineral Oil is intended for use as an overlay for culture of gametes, zygotes, or embryos in Assisted Reproduction Technology (ART) and micro-manipulation procedures.

Intended Users:

- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

Instructions for use:

- GM501 Mineral Oil is a pre-washed ready-to-use oil. No pre-mixing or further preparations are required.
- Prepare dishes and flasks with GM501 Mineral Oil and incubate at 37°C for 5 hours prior to use. Overlay the culture medium with micro drops of GM501 Mineral Oil until completely covered.
- Any laboratory procedures described herein are recommendations only. Each laboratory must establish and validate its own procedures for preparation and use.

Product specifications and quality control:

- Pharmaceutical grade mineral (paraffin) oil.
- All raw materials are of the highest available purity (European Pharmacopoeia and/or USP standard) if applicable.
- A certificate of analysis is available for each batch upon request from our website with respective lot number.
- The SDS for GM501 Mineral Oil is available upon request and can also be downloaded from our website.
- GM501 Mineral Oil is manufactured according to the following specifications:

Density (g/ml)	0.83-0.86
Viscosity (at 30°C/cP)	< 30
Sterility (sterile - SAL 10 ⁻³) Per USP <71>	No Growth
Endotoxins (LAL, EU/ml) Per USP <85>	< 0.25
1-Cell MEA	≥ 80% blastocysts at 120h exposure
Peroxide Value (POV) (mEq/kg)	< 0.10



Precautions:

- Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
- For intended use only.
- Always work under strict hygienic conditions (e.g. LAF-bench ISO Class 5 Environment) to avoid possible contamination.
- The oil may cloud when removed from the incubator and allowed to stand at room temperature.
- This resolves when the oil re-equilibrates. Incubate unused oil promptly. If after several hours oil remains clouded, discard.



Warning:

- All human organic material should be treated as potentially infectious. Handle all specimens as if capable of transmit-

ting HIV or hepatitis. Always wear protective clothing when handling specimens.

Pre-use checks:

- Do not use if upon receipt, the bottle's factory seal is broken or package is opened or defective.
- Do not use if product if it becomes discolored, cloudy or shows evidence of microbial contamination.

Storage instructions and stability:

- The shelf life is 18 months from the date of manufacture.
- Store between 15-25°C.
- Do not freeze before use.
- Keep away from direct sunlight.
- Discard after opening.
- Do not use after expiration date.
- Contents cannot be re-sterilized after opening.

Symbols Glossary*:

	Sterilized using aseptic processing techniques (filtration)		Lot number
	Temperature Limitation		Use by
	Do not use if package is damaged		Catalogue number
	Consult instructions for use		Do not re-sterilize
	By prescription only		Manufactured by
	Caution		Keep away from sunlight

*EN ISO 15223-1:2016, Medical devices - Symbols used with medical device labels

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