



Urgent Field Safety Notice

Device affected: **FertiCult Mineral Oil - lot number FP21FM24**

FSCA-number: **CAPA 2209-03**

Type of action: **Recall - Destroy all stock of FP21FM24**

ID: This is an initial Field Safety Notice.

Date: 8th of November 2022

Attention: Distributors of FertiPro and all professional end-users in specialized laboratories performing ART.

Contact details of local representative for end-users: Please contact your distributor.

Device affected:

Device type: CE marked medical device

Product name: FertiCult Mineral Oil

Lot number: FP21FM24

Production date: 4th of November 2021

Expiry date: 31st of May 2023

Basic UDI¹: 5411967OIL13M

UDI:

Product code	UDI
MINOIL050	(01) 0541196700006 7 (17) 230531 (10) FP21FM24
MINOIL100	(01) 0541196700007 4 (17) 230531 (10) FP21FM24
MINOIL500	(01) 0541196700008 1 (17) 230531 (10) FP21FM24

Intended use: FertiCult Mineral Oil is used to cover media during culturing and/or micro-manipulation of human gametes and embryos.

Order number or order date (for distributor): See accompanying form FP14 F01 provided to distributor

Background:

In the view of strict quality control, the peroxide value (POV) is determined on each lot of incoming raw material oil and on each produced lot of FertiCult Mineral Oil to show the absence of peroxidized unsaturated hydrocarbons which can cause harm to embryos and oocytes. This POV test on FertiCult Mineral oil includes testing of a sample filled in the beginning, in the middle and at the end of the aseptic filling process. Values have to be less than 0.1mEq/kg to release a produced lot for sale.

Description of the problem:

FertiPro recently received a complaint about increased oxidation in FertiCult Mineral Oil - lot FP21FM24. As part of the cause analysis, additional analyses on retained QC-samples of lot FP21FM24 were performed. These showed that QC-samples analyzed of the concerned lot

¹ Note that this batch was CE marked in accordance with the Medical Device Directive 93/42/EEC. Basic UDI is assigned as from FertiCult Mineral Oil batches manufactured in accordance with the Medical Device Regulation 2017/745.



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had an elevated peroxide value that was associated with embryotoxicity (i.e. failed mouse embryo assay).

Although lot FP21FM24 was released according to the specifications, it cannot be ensured that this product still performs well. Therefore, FertiPro decided to start a Field Safety Corrective Action (FSCA) to destroy all stock of FP21FM24.

Action to be taken:

- Please **immediately** destroy all remaining stock of FertiCult Mineral Oil - lot FP21FM24 at your site. Take a photo of the products that will be destroyed and indicate the product codes and number of each product code that were destroyed.
- Please **immediately** forward this Field Safety Notice to any of your customers to whom you have distributed affected product. If English is not an official language in your country, translate this letter and provide the translation to the end-users. Request that they destroy all remaining stock of FertiCult Mineral Oil - lot FP21FM24 and request a confirmation of this within two days.
- For distributor of FertiPro: Complete accompanying form FP14 F01 and return it **within two days** to FertiPro (ra@fertipro.com).

If you still have stock, then FertiPro will replace free of charge.

In order to perform a thorough investigation of this issue, if you already have used FertiCult Mineral Oil - lot FP21FM24 in your procedures, **it would be helpful to receive your feedback and results.**

FertiPro will investigate this incident in-dept and will take appropriate corrective and preventive actions (CAPA), as applicable.

- Raw material is pharma grade oil. To limit toxic oxidative components, two washing steps with ultrapure water are performed during the production process. Fleming *et al.* were the first to demonstrate that embryotoxic mineral oil could be detoxified by washing (Fleming, Pratt, and Braude 1987). Similarly, Lee *et al.* observed improved mouse embryo development using washed oil (Lee *et al.* 2004). In a study by Morbeck *et al.*, washing was beneficial to blastocyst development in MEA tests, as contaminants such as Triton X100 and peroxide were removed (Morbeck *et al.* 2010).
- Since many years, FertiPro routinely performs POV tests and MEA on at least one randomly selected expired batch per year. There have never been indications that safety and performance (including POV and MEA results) of FertiCult Mineral oil would deteriorate during its shelf life of 18 months, even not after stress testing.
- To investigate the root cause of this incident, the raw material used in lot FP21FM24 is re-evaluated as well as FertiCult Mineral oil lots in which the raw material has been



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incorporated, with focus on POV values and outcome of additional mouse embryo assays to be within limits (< 0.1 mEq/kg and $\geq 80\%$ respectively). This evaluation is ongoing, and appropriate actions will be taken when needed.

Recently, FertiPro has even implemented a stricter limits for the POV-value on incoming raw material and FertiCult Mineral oil: < 0.06 mEq/kg

Any questions regarding this Field Safety Notice may be forwarded to ra@fertipro.com. FertiPro remains strongly committed in providing the best possible quality products. We apologize for the inconvenience this situation may have caused.

Thank you for your cooperation,
Kind Regards,

A handwritten signature in black ink, appearing to be "Liesbeth Faes", written over a horizontal blue line.

[Liesbeth Faes \(Nov 8, 2022 16:07 GMT+1\)](#)

Liesbeth Faes
Management Representative
FertiPro NV
Industriepark Noord 32
8730 Beernem
Belgium
SRN number: BE-MF-000000313

Attached to this Urgent Field Safety Notice:

- Attachment 1: FP14 F01_Device recall response form for customers