FertiPro

Urgent Field Safety Notice

Device affected: **FertiCult Mineral Oil - lot number FP21FM28**
FSCA-number: **CAPA 2209-03**
Type of action: **Recall - Destroy all stock of FP21FM28**

ID: This is an initia! Field Safety Notice.

Date: 19th of September 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 medica! device
Product name: FertiCult Mineral Oil
Lot number: FP21FM28
Production date: 13th December 2021
Expiry date: 30th June 2023
Basic UDI1: 5411967OIL13M
UDI:

Product code	UDI
MINOIL050	(01) 0541196700006 7 (17) 230630 (10) FP21FM28
MINOIL100	(01) 0541196700007 4 (17) 230630 (10) FP21FM28
MINOIL500	(01) 0541196700008 1 (17) 230630 (10) FP21FM28
MINOIL050P	(01) 0541196700089 0 (17) 230630 (10) FP21FM28
MINOIL500P	(01) 0541196700088 3 (17) 230630 (10) FP21FM28

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 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 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 of FertiCult Mineral Oil - lot FP21FM28 about decreased embryo development rate and increased number of degenerated embryos. As

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[1] *Note that this batch was CE marked in accordance with the Medica/ Device Directive 93142/EEC. Basic UD/ is assigned as from FertiCult Mineral Oil batches manufactured in accordance with the Medica/ Device Regu/ation 20171745.*

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part of the cause analysis, additional analyses on retained QC-samples of lot FP21FM28 were performed. These showed that two of the three QC-samples analyzed of the concerned lot had an elevated peroxide value that was associated with embryotoxicity (i.e. failed mouse embryo assay).

Although lot FP21FM28 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 FP21FM28.

Action to be taken:

Please **immediately** destroy all remaining stock of FertiCult Mineral Oil - lot FP21FM28 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 FP21FM28 and request a confirmation of this within two days.
Complete accompanying form FP14 F01 and return it **within two days** to FertiPro (ra@fertipro.com).

In order to perform a thorough investigation of this issue, if you already have used FertiCult Mineral Oil - lot FP21FM28 in your procedures, it would be helpful to receive your feedback and results. FertiPro has initiated a CAPA for further investigation and will take appropriate corrective actions, as applicable.

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

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,

N.V.

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... Management
Representative FertiPro NV
Industriepark Noord 32
8730 Beernem
Belgium

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SRN number: BE-MF-000000313

Attached to this Urgent Field Safety Notice:

- Attachment 1: FP14 F01_Device recall response form for customers

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