

<<Name des Kunden>>
To Att. Safety officer / risk manager
<<Adresse des Kunden>>
<<Ort, Land>>

2022-09-20

**URGENT SAFETY INFORMATION
IMPLEMENTATION
PRODUCT RECALL
GM501 Mineral Oil (Batch: OIL-2128)**

Subject: Product recall GM501 Mineral Oil (OIL-2128)

Unfortunately we, Gynemed GmbH & Co. KG as manufacturer, have to inform you that we have to recall the product GM501 Mineral Oil (REF: 4 MO 0100) of batch OIL-2128.

Due to feedback from a customer, tests of the peroxide value (POV) were carried out on reserve samples of the above mentioned batch. The permissible limit was exceeded in some (not all) bottles. Exceeding the specification is associated with embryotoxicity, which has already been confirmed by mouse embryo assays of the reserved samples.

The determination of POV has been a part of Gynemed's quality control for years. It serves to prove that the specification of 0.1 mEq/kg has not been exceeded within the production and at the time of release of the products.

Gynemed is currently conducting an in-depth root cause analysis and will inform you in this regard.

Please ensure in your facility that all users of the above product and other persons to be informed are made aware of this urgent safety information.

Potential safety risk	It cannot be excluded that there is a material or production defect and thus the specified product does not meet the safety and performance specifications. The product could have too high a peroxide value (> 0.1 mEq/kg) and thus cause harm to embryos and oocytes.
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<p>Details of the product concerned</p>	<p>Product name: Gynemed GM501 Mineral Oil REF: 4 MO 0100 Lot: OIL-2128 Production date: 31. Dec 2021 Expiry date: 30. June 2023 Basic UDI: 426017319MOIL93 UDI bottle: (01) 0426017319091 5 (17) 230630 (10) OIL-2128 UDI box: (01) 0426017319410 4 (17) 230630 (10) OIL-2128 Intended Use: GM501 Mineral Oil is a ready-to-use oil for covering the medium during IVF and ICSI procedures. GM501 Mineral Oil prevents its evaporation and stabilizes the pH value.</p>
<p>Safety advice</p>	<p>Do not use the products again. Risks related to a possible increased peroxide level (embryotoxicity) cannot be excluded with certainty.</p>
<p>Product troubleshooting</p>	<p>Product troubleshooting Gynemed GmbH & Co. KG recalls all bottles of GM501 Mineral Oil of the affected batch distributed by them. Destroy the products and please send us a photo showing the number of emptied bottles with article and lot number. - Do this within the next 24 h and please inform us within this time.</p> <p>In case the products have already been used, it would be very helpful for further investigation to receive feedback on the achieved results of the treatments.</p>
<p>Contact details</p>	<p>If you have any questions, please contact Dr. Julia Heinzmann, Phone: +49 (0)4363 9032914; Fax: +49 (0)4363 9032919 Mobile: +49 (0)170 5500193 jhn@gynemed.de</p> <p>Gynemed GmbH & CO. KG Lübecker Str. 9 23738 Lensahn Germany</p>

Enclosed with this letter is the Corrective Action Response Form. Please forward this letter together with the Corrective Action Response Form to the appropriate department(s) at your institution so that they may take note of the information contained herein, determine the need for action, and complete the Response Form.

For distributors

In case you are a distributor of Gynemed GM501 MineralOil. Please confirm to us in writing that you have informed your customers and instructed them to destroy or return the affected lots.

Please return the response form(s) to us within the next 24 hours!

We are extremely sorry if this action causes you any inconvenience and thank you for addressing the matter promptly.

Please contact us immediately if you have any questions.

With kind regards

Dr. Julia Heinzmann
Geschäftsführerin
Gynemed GmbH & Co. KG

PRODUCT RECALL RESPONSE FORM
GM501 Mineral Oil - 4 MO 0100 - (Batch: OIL-2128)

<<Name of the customer>>
<<Address of the customer>>
<<City, Country>>

Subject: Product Recall GM501 Mineral Oil (OIL-2128)

Our records indicate that your facility has received products affected by this product recall.
1. please complete this form and return it by fax or e-mail to the following number/address:
+49 (0)4363 9032919, attention Dr. Julia Heinzmann.

Please note: Please enter "None"/ "0" if you do not have any items to return.

Please remember to attach a photo where the quantity, batch and item number of the product concerned can be seen.

Number of products shipped that are affected by this recall.	Number of items disposed of by the customer
<<eintragen>> items	items

Comments / Feedback:

If you have any questions about this callback, please contact us at:
Tel: +49 (0)4363 9032914
Fax: +49 (0)4363 9032919
E-mail: jhn@gynemed.de

Please confirm that your facility has received the urgent safety information by returning this form to Gynemed GmbH & Co. KG: +49 (0)4363 9032919 (Fax); jhn@gynemed.de (E-Mail)		
Representative of the user's institution	Signature:	Date:
Name and function in block letters		

