



FLUORON® GmbH • Magirus-Deutz-Str. 10 • 89077 Ulm • GERMANY

Sender:

Fluoron GmbH

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Ulm, 11 April 2019

VOLUNTARY PRODUCT RECALL

Affected product: F-Octane
Material number: G-80315 (5ml) / G-80317 (7ml)
Version: Syringe
Lot number: See list attached (Annex I)
Manufacturer: Fluoron GmbH, Magirus-Deutz-Str. 10, 89077 Ulm (DE)

Affected product: F-Decalin
Material number: G-80115 (5ml) / G-80117 (7ml)
Version: Syringe
Lot number: See list attached (Annex II)
Manufacturer: Fluoron GmbH, Magirus-Deutz-Str. 10, 89077 Ulm (DE)

Dear Sir or Madam,

With this letter we would like to inform you about a voluntary product recall. This is a recall of all stocks of the products listed above.

The recall is carried out because the secondary packaging might be perforated by an irregularity in the syringe baking stop variant used. This can impair the sterility of the primary packaging; the sterility of the syringe content remains guaranteed.

No injuries or damages have been reported in connection with this issue.

Measures to be taken immediately by the customer:

According to our documentation, you have received products from the batches mentioned by us. We kindly ask you to track, separate and quarantine these products.

FLUORON® GmbH
Gesellschaft für hochreine Biomaterialien
Sitz der Gesellschaft:
89077 ULM, GERMANY
Geschäftsführer: Volker Geuder
Amtsgericht Ulm HRB 723852
USt-IdNr.: DE812135435

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www.fluoron.de

Commerzbank AG, Ulm
Konto-Nr.: 08 011 588 00
BLZ: 630 800 15
SWIFT-BIC: DRES DE FF630
IBAN: DE56630800 150801158800

Zertifiziert nach DIN EN 13485



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Please confirm with your signature on the enclosed feedback form that you have received this notice and that you have read and understood the necessary measures. We then kindly ask you to return the affected batches to us.

For batches that are returned, a replacement or credit note will be provided. Contact your sales representative of the GEUDER AG to arrange the return of stock and suitable exchange.

Forwarding this notification:

Please ensure in your organisation that all users of the above-mentioned products and other persons to be informed are aware of this notice. If you have delivered the products to third parties, please forward a copy of this information to all affected users and distributors.

Reshipment:

Please address the reshipment to:

GEUDER AG

Hertzstr. 4

69126 Heidelberg

Germany

phone: +49 6221 3066

[Complaint Geuder AG <complaint@geuder.de>](mailto:complaint@geuder.de)

For further information or support please contact Fluoron GmbH via

Email: complaints@fluoron.de, or phone: +49 731 20 55 997 0, or FAX: + 49 731 20 55 997 28.

Please keep this information at least until the action has been completed. We recommend that you keep a copy of this notification and a signed copy of the confirmation form in your files.

This notice has been sent to the relevant regulatory authorities.

We apologize for any inconvenience you, your staff and your patients may experience in this regard. However, Fluoron believes that this is the right step to take. The decision to perform this voluntary recall reflects Fluoron's commitment to high quality standards and an uncompromising commitment to patient safety.

Yours sincerely,

Dr. Wilfried Kugler

- Safety Officer for Medical Devices -

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Annex I / affected lots of F-Octane

VOLUNTARY PRODUCT RECALL

Affected Product: F-Octane
Material number: G-80315 (5ml) / G-80317 (7ml)
Version: Syringe
Lot number: See list below
Manufacturer: Fluoron GmbH, Magirus-Deutz-Str. 10, 89077 Ulm (DE)

Artikelnummer:	Chargennummer:
G-80315 (5ml)	5S300315
G-80315 (5ml)	5S040515
G-80315 (5ml)	5S280715
G-80315 (5ml)	5S280715B
G-80315 (5ml)	5S240815
G-80315 (5ml)	5S080216
G-80315 (5ml)	5S080216B
G-80315 (5ml)	5S071116
G-80315 (5ml)	5S071116B
G-80315 (5ml)	5S060217
G-80315 (5ml)	5S060617
G-80315 (5ml)	5S060617B
G-80315 (5ml)	5S070817
G-80315 (5ml)	5S161017
G-80315 (5ml)	5S080118
G-80315 (5ml)	5S140518
G-80315 (5ml)	5S130818

Artikelnummer:	Chargennummer:
G-80317 (7ml)	7S300315
G-80317 (7ml)	7S040515
G-80317 (7ml)	7S030815
G-80317 (7ml)	7S240815
G-80317 (7ml)	7S240815B
G-80317 (7ml)	7S080216
G-80317 (7ml)	7S290816
G-80317 (7ml)	7S290816B
G-80317 (7ml)	7S071116
G-80317 (7ml)	7S200217
G-80317 (7ml)	7S060617
G-80317 (7ml)	7S080517
G-80317 (7ml)	7S170717B
G-80317 (7ml)	7S070817B
G-80317 (7ml)	7S161017
G-80317 (7ml)	7S080118
G-80317 (7ml)	7S200318
G-80317 (7ml)	7S140518
G-80317 (7ml)	7S130818B

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Annex II / affected lots of F-Decalin

VOLUNTARY PRODUCT RECALL

Affected product: F-Decalin
Material number: G-80115 (5ml) / G-80117 (7ml)
Version: Syringe
Lot number: See list below
Manufacturer: Fluoron GmbH, Magirus-Deutz-Str. 10, 89077 Ulm (DE)

Artikelnummer:	Chargennummer:
G-80115 (5ml)	5S 200415
G-80115 (5ml)	5S010615
G-80115 (5ml)	5S210915
G-80115 (5ml)	5S270416
G-80115 (5ml)	5S260916
G-80115 (5ml)	5S260916C
G-80115 (5ml)	5S191216
G-80115 (5ml)	5S060317
G-80115 (5ml)	5S250917
G-80115 (5ml)	5S220118
G-80115 (5ml)	5S280518
G-80115 (5ml)	5S160718

Artikelnummer:	Chargennummer:
G-80117 (7ml)	7S200415
G-80117 (7ml)	7S070715
G-80117 (7ml)	7S130715
G-80117 (7ml)	7S130715B
G-80117 (7ml)	7S191015
G-80117 (7ml)	7S191015B
G-80117 (7ml)	7S250116
G-80117 (7ml)	7S150216
G-80117 (7ml)	7S150216B
G-80117 (7ml)	7S090516
G-80117 (7ml)	7S090516B
G-80117 (7ml)	7S260916
G-80117 (7ml)	7S041016
G-80117 (7ml)	7S241016
G-80117 (7ml)	7S160117
G-80117 (7ml)	7S130217
G-80117 (7ml)	7S240417
G-80117 (7ml)	7S240417B
G-80117 (7ml)	7S060617
G-80117 (7ml)	7S170717
G-80117 (7ml)	7S170717B
G-80117 (7ml)	7S110917
G-80117 (7ml)	7S140817
G-80117 (7ml)	7S061117
G-80117 (7ml)	7S080118
G-80117 (7ml)	7S260318
G-80117 (7ml)	7S160518
G-80117 (7ml)	7S280518
G-80117 (7ml)	7S090718
G-80117 (7ml)	7S270818
G-80117 (7ml)	7S270818B

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Annex III / Customer feedback

VOLUNTARY PRODUCT RECALL

Affected product: F-Octane
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Version: Syringe
Lot number: See list attached (Annex I)
Manufacturer: Fluoron GmbH, Magirus-Deutz-Str. 10, 89077 Ulm (DE)

Affected product: F-Decalin
Material number: G-80115 (5ml) / G-80117 (7ml)
Version: Syringe
Lot number: See list attached (Annex II)
Manufacturer: Fluoron GmbH, Magirus-Deutz-Str. 10, 89077 Ulm (DE)

Dear Sir or Madam,

We hereby confirm that we have read and understood your voluntary product recall dated 11 April 2019 and that we have informed all affected persons in our facility. We have discontinued the further use and distribution of the existing production batches with immediate effect. Products still in stock or returned to us will be immediately returned to Geuder AG. For the return delivery we request a

credit note

or

replacement

Yours sincerely,

Customer's / dealer's name:

Address:

ZIP / City:

Country:

Document completed by:

Phone:

E-Mail:

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