

Ponte San Nicolò, February 8th, 2022

Urgent Field Safety Notice

Commercial name of the affected device:

Product	Description	Volume	Ref. Number	Lot number
GOT Multi C ₂ F ₆	Pure hexafluoroethane, multidose cylinder	75 ml	GOT 008-00	P21050002

Company-identifier: **FSN000324** (related to CLAIM000324 on lot P21050002)

Type of action: return of the medical device

Dear Distributor, dear Health Care Professional,

the purpose of this letter is to inform you that AL.CHI.MI.A. srl (ALCHIMIA) is recalling one lot (P21050002) of GOT 008-00, ophthalmic gas used for long-term intraocular tamponade in vitreoretinal surgery, due to a lack of correspondence between the cylinder label and the blister tray/packaging box' labels.

ALCHIMIA records indicate that your company has received one or more pieces of the lot of the device listed above, potentially affected by this issue. No other product model or lot numbers are involved in this problem.

Description of the issue

The issue is relevant to GOT Multi C₂F₆ lot P21050002 (ref. GOT 008-00).

Specifically, the cylinder GOT Multi SF₆, lot P21050001, was found inside the blister and box both labelled as GOT 008-00 lot P21050002 GOT Multi C₂F₆.

The pictures reported in Attachment 1 of the present communication show the lack of correspondence between the cylinder (GOT Multi SF₆) and the blister tray and the packaging box, both relevant to lot P21050002 of product GOT Multi C₂F₆.

The volume of the pure gas to be withdrawn to obtain a non-expansile concentration for a tamponade effect is different for each ophthalmic gas. Specifically,

- for GOT Multi SF₆ (GOT 007-00), a non-expansile 20% concentration is obtained withdrawing 10 ml of gas that is mixed with 40 ml of air,
- for GOT Multi C₂F₆ (GOT 008-00), a non-expansile 16% concentration is obtained withdrawing 8 ml of gas that is mixed with 42 ml of air.

This information is reported in the relevant Instruction of Use of our products GOT Multi (ref. MCM-231 rev. 6).

During a retinal detachment surgery, GOT multi SF6 gas was used instead of declared GOT multi C2F6 (lot P21050002) in one patient, as notified by ANSM on February 4th, 2022 (ref. R2203865). No adverse effect for the patient was reported.

Advise on action to be taken by the distributor

To mitigate risks associated with this issue, ALCHIMIA is now requesting to carry out the following actions:

- Maintain this notice in your records.
- Immediately identify and quarantine the following listed product in your inventory.

Product	Description	Volume	Ref. Number	Lot number
GOT Multi C ₂ F ₆	Pure hexafluoroethane, multidose cylinder	75 ml	GOT 008-00	P21050002

- Fill in the “Distributor Initial Questionnaire” (ref. Attachment n. 2A) and return to ALCHIMIA within two (2) days from receipt of this notice.
- Return all pieces of lot P21050002 of GOT multi C2F6 (ref. GOT 008-00) present in your inventory to ALCHIMIA. Our company will assist you as necessary in initiating the return and replacement of this product.
- Transmit immediately this notice to all end users (health-care professionals) to whom the potentially affected devices have been delivered.
- Request from the end users to fill-in the “End user questionnaire” (ref. Attachment n. 3) and to return back the “End user questionnaire” within February 22nd, 2022.
- Fill in the “Distributor Follow-up Questionnaire” (ref. Attachment n. 2B), with all the information gathered by the end user and return it to ALCHIMIA within February 28th, 2022.

Advise on action to be taken by the end user (health care professional)

To mitigate risks associated with this issue, ALCHIMIA, through ALCHIMIA’s local representative (the distributor), is now requesting to carry out the following actions:

- Maintain this notice in your records.
- Immediately identify and quarantine the listed product in your inventory.

Product	Description	Volume	Ref. Number	Lot number
GOT Multi C ₂ F ₆	Pure hexafluoroethane, multidose cylinder	75 ml	GOT 008-00	P21050002

- Count each piece of the lot present in your inventory.
- Verify each piece of the lot: open each box, verify the cylinder inside the blister tray.
- If the cylinder is labelled with SF6 (GOT Multi SF6), destroy the affected piece, if any.
- If the cylinder is labelled with C₂F₆ (GOT Multi C₂F₆), use the product safely, according to the Instructions of Use enclosed in the box.
- Fill-in the "End user questionnaire" (ref. Attachment n. 3)
- Return the questionnaire to your ALCHIMIA local representative within February 22nd, 2022.

Your ALCHIMIA local representative will replace the destroyed pieces of GOT Multi C₂F₆.

Additional Information:

ALCHIMIA will notify the Competent Authority of this action accordingly.

In alignment with our Mission, ALCHIMIA is committed to patient safety and continues to investigate the cause of this issue.

We appreciate your prompt attention to this matter and we sincerely apologize for any inconvenience this may have caused. If you have any questions regarding this communication, please contact:

qa@alchimiasrl.com,

AL.CHI.MI.A. srl, Viale Austria 14, 35020 Ponte San Nicolò

Sincerely,

List of Attachments:

Attachment n. 1 – Photos of the affected device (GOT 008-00 lot P21050002)

Attachment n. 2A – “Initial Distributor Questionnaire”, form to be filled-in by the distributor and returned to ALCHIMIA.

Attachment n. 2B – “Follow-up Distributor Questionnaire”, form to be filled-in by the distributor and returned to ALCHIMIA.

Attachment n. 3 – “End user Questionnaire”, form to be filled-in by the end user and returned to ALCHIMIA’s local representative (the distributor).

ATTACHMENT n. 1 Photos of the affected device (GOT 008-00 lot P21050002)



Figure n. 1

Photo of the gas cylinder in the blister tray of lot P21050002 of GOT 008-00 (front side)

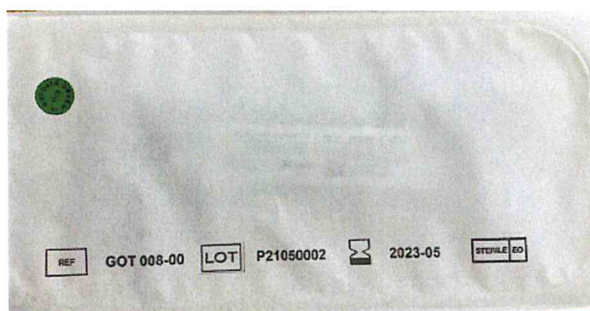


Figure n. 2

Photo of the gas cylinder in the blister tray of lot P21050002 of GOT 008-00 (back side)



Figure n. 3

Photo of the box of lot P21050002 of GOT 008-00

ATTACHMENT n. 2A to FSN000324

Please complete this form and return **within two (2) days from receipt of notice** to
 E-mail: qa@alchimiasrl.com
 Fax: + 39 049 8962071

Initial Distributor Questionnaire
 to
ALCHIMIA Urgent Field Safety Notice (FSN000324)

- We have received the Field Safety Notice and confirm that we have quarantined the stock and wish to return the following:

Product	Ref. Number	Lot number	Quantity of pieces received from ALCHIMIA	Quantity of pieces in inventory to be returned to ALCHIMIA
GOT Multi C ₂ F ₆	GOT 008-00	P21050002		

- We have not shipped any products affected by this Field Safety Notice to third parties.

- We have notified our end users who have already received the lot affected by this recall notice in order to arrange destruction of any affected piece of the mentioned lot.

Product, (Ref. Number)	Lot number	End user <i>Address</i>	Quantity of pieces delivered to end user
GOT Multi C ₂ F ₆ (GOT 008-00)	P21050002		

NAME:
 TELEPHONE NUMBER.....
 POSITION:
 DISTRIBUTOR COMPANY NAME (or STAMP).....
 DATE:
 SIGNATURE:

ATTACHMENT n. 2B to FSN000324

Please complete this form and return within **February 28th, 2022** to

E-mail: qa@alchimiasrl.com

Fax: + 39 049 8962071

Follow-up Distributor Questionnaire
to
ALCHIMIA Urgent Field Safety Notice (FSN000324)

We have notified our end users who have already received the lot affected by this recall notice in order to arrange destruction of any affected products.

We hereby provide ALCHIMIA with a detailed list of pieces of lot P21050002 GOT Multi C2F6.

Product, (Ref. Number)	Lot number	End user <i>Address</i>	Quantity of pieces delivered to end user	Quantity of pieces "affected by the issue" and destroyed by end user
GOT Multi C ₂ F ₆ (GOT 008-00)	P21050002			

..... *(detail number)* questionnaires filled-in and received by end users are hereto attached.

NAME:

TELEPHONE NUMBER.....

POSITION:

DISTRIBUTOR COMPANY NAME (or STAMP).....

DATE:

SIGNATURE:

ATTACHMENT n. 3 to FSN000324

Please complete this form and return within **February 22nd, 2022** to

Name and Address of ALCHIMIA local representative

Fax: *to be reported*

E-mail: *to be reported*

End User Questionnaire

in relation to

ALCHIMIA Urgent Field Safety Notice (FSN000324)

We have been notified by our ALCHIMIA local representative to arrange destruction of any affected pieces in our inventory relevant to lot P21050002 (GOT Multi C2F6, GOT 008-00). We report hereto below the detailed list of pieces of lot P21050002 (GOT Multi C2F6, GOT 008-00) affected and destroyed.

Product, (Ref. Number)	Lot number	Quantity of pieces in end user inventory	Quantity of pieces "affected" and destroyed
GOT Multi C ₂ F ₆ (GOT 008-00)	P21050002		

We hereby declare to have destroyed the affected pieces of GOT 008-00 lot P21050002 GOT Multi C2F6.

NAME:

TELEPHONE NUMBER.....

POSITION:

COMPANY NAME (or STAMP)

DATE:

SIGNATURE: