Urgent Field Safety Notice
Urgent safety information
FSN 2-2025
25.02.2025

Please forward to all
end users of the products!

Dear customer,

This letter is to advise you that Chromsystems Instruments & Chemicals GmbH is taking corrective action on the product listed in Table 1. Our records show that you have been supplied with the listed product.

Table 1: Affected products / batches.

Product designation	Order no.	Batch no.
Mobile Phase A MassChrom® Amino Acid Analysis	75001	#0225

Description of the problem including the identified cause

Information from a customer feedback and internal investigations confirm a strong loss of intensity for several analytes (e.g. 4-Hydroxyproline, α-Aminoadipic acid, Asparagine, Glutamic acid, Glutamine, Homocitrulline, Proline, Sarcosine, Serine, Threonine) when using Mobile Phase A (order no. 75001) of batch #0225 compared to phases of previous batches. This can therefore lead to problems when determining the concentration, particularly in low concentration ranges (LLOQ).

Furthermore, after only few injections, retention time shifts for Histidine, Arginine and Ornithine, and separation problems for 1-Methylhistidine and 3-Methlyhistidine can occur.

Therefore, please observe and follow the measures listed below for Mobile Phase A (order no. 75001) of batch #0225.

We assess the risk on the basis of following considerations

Due to the low intensities and the retention time shifts and separation problems that occur, we do not consider reliable analysis to be guaranteed when using Mobile Phase A (order no. 75001) of batch #0225.

Due to the loss of intensity, analyte peaks can become so small that it is no longer possible to determine their content. The shift in retention times can lead to peaks of 1-Methylhistidine and 3-Methylhistidine being superimposed or analytes no longer being detected in the stored retention time window.

Therefore, do not use the product listed in Table 1 for analytical determinations.

What measures are to be taken by the customer/user?

- Do not use Mobile Phase A (order no. 75001) of batch #0225 and send us back the affected product or destroy it.
- In case you already have used Mobile Phase A according to Table 1, send us back the analytical column (order no. 75100) used in this purpose. We will provide a replacement column.
- We are currently unable to offer you a replacement product for Mobile Phase A. However, production of a follow-up batch of the Mobile Phase A (order no. 75001) has already started. As soon as this lot is finally approved, you will receive a replacement delivery by express delivery.
- Please ensure that all users of the above products and other persons in your organisation who need to be informed are made aware of this "Urgent Safety Information".
- If you have given any of the products mentioned in this letter to another laboratory, inform that laboratory of the contents of this letter and forward a copy or inform us by e-mail at regulatory@chromsystems.com.

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Managementsystem zertifiziert nach:
ISO 9001, ISO 13485 (including MDSAP)

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– Please document your actions on the enclosed response form and please return the reply form by 10.03.2025.

Passing on the information described here

Please follow this notice and the resulting action to ensure the effectiveness of the corrective action and keep this information at least until the action is completed.

The competent national regulatory authority has been informed of this "Urgent Safety Information".

If you have any questions, please contact our support team at +49 89 18930-111 or by e-mail at support@chromsystems.com.

We apologise for the inconvenience caused by this situation. Chromsystems support is always available to answer any further questions you may have and will deal with your request quickly and reliably.

We thank you in advance for your support in carrying out the necessary measures and look forward to continuing our good cooperation.

Yours sincerely,

Dr. Ralf Fischer
Head of Regulatory Affairs Department
Chromsystems Instruments & Chemicals GmbH

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CHROMSYSTEMS
DIAGNOSTICS BY HPLC & LC-MS/MS

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Reply form

Product designation	Order no.	Batch no.
Mobile Phase A MassChrom® Amino Acid Analysis	75001	#0225

1. Customer information (to be filled in by the customer)

Organisation	
Address	
Contact Name	
Title/Function	
Phone	
Email	

2. Customer action (to be filled in by the customer)

☐	The information that Mobile Phase A (order no. 75001) of batch #0225 must not be used has been implemented and brought to the attention of all relevant users.	To be completed by the client or enter n/a.
	Following amount of bottles 75001 #0225 ☐ should be sent back to Chromsystems (pick-up order by Chromsystems). ☐ have been destroyed on site.	Amount of bottles:
☐ Yes ☐ No	I have already used Mobile Phase A (order no. 75001) batch #0225.	Chromsystems will additionally provide a new replacement column in exchanged for used column.
☐ Yes ☐ No	Are you aware of any adverse medical events and direct negative effects on patients related to the product listed in this safety communication? If "yes": Please provide details of this event (to be completed by the client):	
☐ Yes ☐ n/a	I have identified and notified my customers or other affected third parties to whom products affected by this letter were shipped or may have been shipped.	Enter the date and type of notification or n/a.
☐	I have a question, please contact me.	Short description of the request:

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Please forward to all
end users of the products!

With my signature, I acknowledge receipt of Safety Notice FSN 02-2025 and that I have read and understood its contents.	
Name	
Signature	
Date	

Please return the completed form by e-mail or fax by 10.03.2025 to:

E-mail: regulatory@chromsystems.com / Fax: +49 89 189 30 199

It is important that your organisation takes the actions listed in the FSN and confirms that you have received the FSN.

Your organisation's response is the evidence we need to monitor the progress of the corrective action.

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