

Rev 1: September 2018

FSN Ref: FSN_2023_10_Phosphorus Inorganic FSCA_2023_10_Phosphorus Inorganic

Date: 13th October 2023

Urgent Field Safety Notice

Phosphorus Inorganic, Molybdate

For Attention of*: all distributors, end users, medical practitioners using concerned reagent or results obtained with concerned reagent

Contact details of local representative (name, e-mail, telephone, address etc.)*

DIALAB - Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H. IZ-NOE Sued, Hondastrasse, Objekt M55 2351 - Wr. Neudorf, AUSTRIA

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Urgent Field Safety Notice (FSN)

Phosphorus Inorganic, Molybdate

Risk of falsified results

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	Phosphorus Inorganic, Molybdate is a Diagnostic reagent for quantitative in vitro determination of phosphorus in human serum, plasma or urine on photometric systems.
1	2. Commercial name(s)
.	Phosphorus Inorganic, Molybdate
1	3. Unique Device Identifier(s) (UDI-DI)
.	-
1	4. Primary clinical purpose of device(s)*
.	Measurement of phosphorus in serum and urine is mainly performed to detect disorders of kidneys, bones and parathyroid glands.
1	5. Device Model/Catalogue/part number(s)*
.	REF: D00359B, D00361, D00362, D00363, D00364, D0435917, D85911, DA0840, DB20329, DE1840, DT1040.
1	6. Software version
.	-
1	7. Affected serial or lot number range
.	Phosphorus Inorganic, Molybdate Lot. 2156/925247, Exp.: 31.10.2025

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	In the course of investigations in the context of a customer complaint, it was determined that the reagent Phosphorus Inorganic, Molybdate in the mentioned product batch shows signs of reduced product stability. This is manifested by the appearance of turbidity in the reagent.
2	2. Hazard giving rise to the FSCA*
.	A possible impairment of product quality and a possible patient risk cannot be ruled out.
2	3. Probability of problem arising
.	The product of all items in the lot number mentioned is to be regarded as impaired, especially in case of turbidity of the reagent. Depending on age, storage and transport conditions, there is an increasing risk of adulterated results occurring.
2	4. Predicted risk to patient/users
.	Due the quality issue of Phosphorus reagent, there is a potential for inaccurate phosphorus results to be generated. Thus, if you receive results that do not match with other clinical data, such as symptoms, patient history, or other test results, then please repeat the test with another batch of product.

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3. Type of Action to mitigate the risk*		
3.	1. Action To Be Taken by the User* ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification/inspection ☒ Follow patient management recommendations ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☒ Other ☐ None All Users: - Make sure that the Field Safety Notice related to the actual FSCA gets forwarded to all customers and final customers - Make sure that Phosphorus Inorganic, Molybdate of concerned reagent does not get sold anymore. - You will be informed by DIALAB about the further procedure (Credit note/replacement). - Undersign in the confirmation form attached to this FSN (Annex 1) and send the filed out signed form to safety@dialab.at: You undersign, that all required actions have been implemented for and all concerned parties have been made aware of this Field Safety Notice. Final customers: - Make sure that every further measuring with that Phosphorus Inorganic, Molybdate of concerned reagent gets stopped immediately. - Review your recent measurements with the concerned product in the context of a possible influence on patient treatment by the responsible physician and contact the physician with this Field Safety Note in any doubt.	
3.	2. By when should the action be completed?	2023-11-08
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes Evaluation of recent measurements about a possible patient risk, and where required contact with medical practitioner, eventual repeat of analysis with non-concerned reagent	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes, reply until 2023-11-08

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4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	4. List of attachments/appendices:	Annex 1: Customer Reply Form
4.	5. Name/Signature	Lorenz Miller, MSc.

Transmission of this Field Safety Notice	
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Confirmation Form

Phosphorus Inorganic, Molybdate
FSCA-Identifier: FSCA_2023_10_Phosphorus Inorganic



Destruction

Distributor/Customer Details:

Company Name	
Address	

Total Quantity:

Received	
Distributed	

The undersigned confirms that all required actions have been implemented for and all concerned parties have been made aware of this Field Safety Notice.

Completed By	
Telephone / E-Mail	
Date	
Original Signature	

Please complete this form and send it via e-mail until **2023-11-08** to safety@dialab.at.

Thank you for your efforts!