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Document No.:	CORP-TEMP-0018	Revision:	0	Effective Date:	Mar 31, 2021

Quality Assurance
VWR International SAS
Immeuble Estréo
1-3 rue d'Aurion
93114 ROSNY-SOUS-BOIS CEDEX

9th November 2022

URGENT Field Safety Notice - FA-2022-000146

Dear Customer,

We contacted you previously regarding a potential quality issue relating to FA-2022-000146 concerning the following product and lot. The purpose of this letter is to provide you with further details on this issue.

Part Number	Lot	Description
VWRQFOR0020AF59001	220707C003	FORMALINE 10% QPATH® 5ML IN 20CC POT.

Initially, we requested that you immediately quarantine any stock of the above listed lot and return a response form to confirm receipt of the notification. If you have not already quarantined this product/lot, please do so immediately.

This Field Safety Notice has been issued because some of VWRQFOR0020AF59001, lot 220707C003 has been shown to have a low concentration of Formaline.

Investigation has shown that the concentration of Formaline of some of this lot is ranging between 0.02-0.04% and not 4% as stated in the description of the product.

If this product is used, there is a risk that samples may not be fixated and tissue will not be preserved.

As a precaution, we are asking customers to dispose of this product/lot.

Corrective Actions to be taken by the user


If you have not used any of this product/lot, please complete the attached response form in order to receive credit/replacement as appropriate

If you have used this product, please evaluate the impact of this non-conformity against your application. Complete the attached response detailing quantity used and quantity remaining, and we will provide a full credit or replacement as required.

The relevant Regulatory Authorities have been informed of this matter.

Corrective and Preventive are being implemented internally.

Please accept our apologies for any inconvenience caused as a result of this occurrence. If any further information is required, please do not hesitate to contact esther.venmans@avantorsciences.com or anna.szuba@avantorsciences.com

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Kind regards,

Quality Assurance Manufacturing

Esther Venmans



HISTORY

Revision No.	Changes	Reason
0	New document	New document

FOLLOW UP RESPONSE FORM

Field Safety Notice FA-2022-000146 - VWRQFOR0020AF59001 - FORMALINE 10% QPATH® 5ML 20CC POT

- Please fill out the details below & email back to us **before 18th November 2022**. Thank you!
- Return this form by e-mail to: productalert.handling@vwr.com

Concerned Product: VWRQFOR0020AF59001 - FORMALINE 10% QPATH® 5ML 20CC POT
Lot Nr: 220707C003

Hereby we confirm to have checked our products and (*)

- We confirm **all the above listed stock was quarantined and not used. We will dispose of the stock and provide a certificate of disposal and request a full credit.**

Concerned Article	Description	Lot Number	Quantity disposed (*)
VWRQFOR0020AF59001	FORMALINE 10% QPATH® 5ML 20CC POT	220707C003	

- We confirm **some of the above listed stock was used. We have assessed the impact of this non-conformity against our application. We will dispose of the remaining stock and provide a certificate of disposal and request a full credit.**

Concerned Article	Description	Lot Number	Quantity Used(*)	Quantity Disposed(*)
VWRQFOR0020AF59001	FORMALINE 10% QPATH® 5ML 20CC POT	220707C003		

Customer Number	
Customer Name	
Department:	
Contact name:	
Telephone:	
E-mail:	
Collection Address:	
Postal code:	
City:	
Country:	

I, the undersigned, hereby confirm that I have been informed about the non-conformity of the above-mentioned products. In the event of failure to comply with the instructions, any usage of the faulty lot shall be the sole responsibility and liability of the user.

(*) These fields are mandatory to process the claim faster.

Name/Function	Function	Signature	Date