



SAV Liquid Production GmbH - Hochriesstr. 2 - 83126 Flintsbach a. Inn

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SAV Liquid Production GmbH

Hochriesstr. 2
D-83126 Flintsbach a. Inn
Germany Fon +49 (0)8034-90980-0 Fax + 49 (0)8034-90980-70
www.sav-lp.de
Email: info@sav-lp.de

Flintsbach, 21.08.2024

Urgent safety information / recall of a medical device

Affected products:

- Formaldehyde solution 4% buffered, neutral; Item number FN-60180-4-1;
Lot 12489964 (date of manufacture 2024-07)
- Formaldehyde solution 4.5% buffered, neutral; Item number FN-60180-45-1;
Lot 12443377 (date of manufacture 2024-05)

Dear Ladies and Gentlemen,

this letter contains important information that requires your immediate attention.

Reason for the security notice:

In the course of market surveillance, SAV Liquid Production GmbH became aware that the formaldehyde solution could leak from the above-mentioned in-vitro diagnostics if the vessels are stored overhead for a longer period of time.

According to the current state of knowledge, there is no risk to the performance of the product, as the samples should not be at risk even in the event of minor leaks. However, please always remember to wear protective gloves and goggles when working with the product.

Measures taken by the user:

Please stop using the mentioned items with immediate effect.

Please return the affected items to your retailer. You can also destroy the items on site.

Please return the enclosed **feedback form** to us immediately after taking note of this security letter.

Disclosure of the information described here:

Please ensure in your organization that all users of the above articles and other persons, which have to be informed are aware of this urgent security information. If you have transferred the products to a third party, please forward a copy of this information or inform the contact persons listed below.

Please keep this information at least until the measure has been completed.

Bank name: meine Volksbank Raiffeisenbank eG
Cto.-No. 1710486, P. 71160000
BIC GENODEF1VRR
IBAN DE36 7116 0000 0001 7104 86
UstIDNr: DE273709973 Steuer number:
156/137/10180

Place of jurisdiction: Rosenheim
Handelsregister: HRB 20423
Firmensitz: Flintsbach a. Inn
Managing Director: Leonhard Schliersmaier

Hochriesstr. 2
83126 Flintsbach a. Inn
Phone: +49(8034)90980-0
Fax: +49(8034)90980-70



The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this "Urgent Safety Information".

Contact person:

If you have any questions, please contact

Leonhard Schliersmaier
Managing Director and PRRC
Phone: 49 (0) 8034-90980-0
Fax: 49 (0) 8034-90980-70
info@sav-lp.de

For SAV Liquid Production GmbH, the quality and performance of our products is our top priority. We apologize for any inconvenience you may have caused as a result of this situation and thank you in advance for your assistance in resolving this issue as quickly as possible.

Best regards,

Leonhard Schliersmaier
Managing Director and PRRC

Dr. Angela Wölfel
Quality Management Officer

Attachment: Feedback on the safety information



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Feedback on the safety information

Possible leakage of formaldehyde solution 4% (4.5%) buffered, neutral

Customer	
Name of the institution:	
Street, house no.:	
Zip code, city:	
Land:	

- We will return the products still with us in consultation with the SAV service department (service@sav-lp.de) **by 30.09.2024 at the latest.**
- There are no more affected products in our facility that would need to be destroyed or returned.

- I have read and understood the safety information and confirm this with my signature. All users and other persons in my institution who need to be informed have become aware of this letter.

Name (in block letters): _____

Function (in block letters): _____

Date: _____

Signature: _____

Please send this feedback form by fax, email or postage to:

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