

Market Withdrawal

17 April 2023

Notification Number: CCNS-1004391

The purpose of this Market Withdrawal is to inform you of an issue impacting product(s) purchased by your company. A copy of this letter should be forwarded immediately to the personnel in your organization that utilize this product.

Affected Product(s)

Item No.	Item Description	Lot / Batch
900666-	Bruker standard solvent - 50% ACN + 47.5%	SHBQ1324
100mL	H2O + 2.5% TFA suitable for MALDI-MS	

Description of the Issue

MilliporeSigma has been notified of application issues related to the Bruker Standard Solvent Solution - 50% ACN + 47.5% H2O + 2.5% TFA suitable MALDI-MS not performing as intended. This issue is isolated to 900666-100mL batch: SHBQ1324.

Reason for the Notification

This material is being withdrawn from the market as it is not performing as intended for MALDI-MS applications. The trifluoroacetic acid (TFA) used in production of the solution does not meet specification.

Corrective Action

The trifluoroacetic acid (TFA) used in the production of the Bruker Standard Solvent Solution will have a retest date implemented to prevent the usage of aged and/or compromised material in production. Additional controls have been implemented in the manufacturing instructions to prevent the use of aged TFA in 900666-100mL.

Required/Recommended Action

Please immediately examine your inventory to determine if you have any remaining impacted product and forward a copy of this letter to the personnel in your organization that utilize this product and/or need to be made aware of this issue. Please dispose of this material through your waste stream as it is not functioning as intended.

In addition, if you may have further distributed this product, please identify your customers and notify them at once of this issue. Your notification to customers should include a copy of this notification.

Additional Information

None

Attachments

None

Customer notifications are created by an electronic tool that allows evaluation and approval through our documented systems by representatives from Product Management and Quality. Therefore, this document is valid without signature.

If you would like more information about this customer notification, please contact your local representative or use the link https://www.sigmaaldrich.com/offices for our website to obtain the phone number and/or email address of your local office.

We apologize for any inconvenience that this issue may cause you. Thank you for your loyal business.