



October 21, 2020

Re: Quality Notice NC-44605761

Dear Customer,

This letter is to provide additional information responsive to your inquiry regarding the Quality Notice you received dated October 15, 2020 regarding (-)-Delta 9 THC Certified Reference Material, T-005-1ML lot FE08221804.

The purpose of this notice is to clarify that the Certified Concentration of T-005-1ML lot FE08221804 remains the same as stated on the COA (1.001 mg/mL). The uncertainty value for this lot as reported on the COA has been expanded from 0.033 to 0.078 mg/mL.

The Certified Concentration for this lot with the expanded uncertainty value is 1.001 ± 0.078 mg/mL and has been updated on the COA.

The following FAQ may help to further guide you:

Is this due to a stability issue? **No, this change is not due to stability, the expiration date will not be restated.**

Was there a product recall? **No, this was not a product recall.**

How does this affect ISO 17025 application customers? **In ISO 17025 applications customers may need to address the propagation of the uncertainty of the calibrator into the uncertainty of their methods.**

How was this detected? **This was detected during lot to lot comparison which was reported on the COA.**

As stated above, the original certified concentration value of lot FE08221804 remains the same, however with an expanded uncertainty.

If you have any questions, please contact MilliporeSigma's (Cerilliant Corporation's) Technical Service at 1-800-848-7837 or at Cerilliant-techserv@milliporesigma.com.

Best regards,

Lara Sparks
Quality Director





RECEIVED

OCT 28 2020

WSP TOX LAB

Quality Notice

15 October 2020

Notification Number: NC-44605761

The purpose of this *Quality Notice* 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
T-005-1ML	(-)-Δ9-THC	FE08221804

Description of the Issue

T-005-1ML, (-)-Δ9-THC lot FE08221804 is approximately 4% to 5% low when compared to the new lot FE02072001. Analysis of lot FE08221804 of (-)-Δ9-THC to a new calibration curve yields a result of 0.943 mg/mL. The product was released with a certified value stated on the COA of 1.001 mg/mL.

Reason for the Notification

The difference in the lot-to-lot comparison was identified when the new lot FE02072001 was released. An analyzed value of 0.943 mg/mL for lot FE08221804 was reported on the COA.

Corrective Action

Mass balance purity factor was used to assign the value to the stock solution. Prior lots were assigned a value using an assay to an independently prepared calibrator. When comparing the new lots of T-005-1ML, the analyzed values are higher in concentration to the previous lots. It was determined that use of the assay for value assignment on prior lots led to a drift in the assay value over time, that was not detected within the specifications.

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.

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.

Merck KGaA, Darmstadt, Germany
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
Phone +49 6151 72-0

Sigma-Aldrich Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
3050 Spruce Street
St. Louis, MO 63103, USA
Phone +1 (800) 521-8956 +1 (314) 771-5765

EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive
Burlington, MA 01803, USA
Phone +1 (781) 533-6000

Additional Information

If you have any questions, please contact MilliporeSigma's (Cerilliant Corporation's) Technical Service at 1-800-848-7837 or at Cerilliant-techserv@milliporesigma.com.

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 www.emdmillipore.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.

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Corporation with General Partners
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