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URGENT FIELD SAFETY NOTICE

ThermoScientific™ Oxoid™Mueller Hinton Broth CM0405B Lots 1833157 (D.O.M 09.03.2016) and 1865331 (D.O.M 18.05.2016)

Customers are to be advised of the following:

DESCRIPTION
An internal technical investigation by Oxoid Limited, part of Thermo Fisher Scientific, has confirmed that ThermoScientific™ Oxoid™ Mueller Hinton Broth, CM0405B Lots 1833157 and 1865331 have incorrect cation information detailed on the product label.

Lot: 1833157
Current values: 2.120 mg Ca++ per litre; 0.674 mg Mg++ per litre
Correct values: 3.801 mg Ca++ per litre and 5.765 mg Mg++ per litre.

Lot: 1865331
Current values: 2.172 mg Ca++ per litre; 0.769 mg Mg++ per litre.
Correct values: 3.276 mg Ca++ per litre and 4.809 mg Mg++ per litre

Mueller-Hinton Broth requires supplementation with the divalent cations Mg++ and Ca++ after sterilisation. The CLSI recommend the following cation levels Ca++, 20-25mg/litre and Mg++, 10-12.5mg/litre.

The risk, therefore, is that the user, because of the lower cation concentration indicated on the label, may adjust the cation concentration to a level higher than that recommended by the CLSI.

Continued use of the lots, utilising incorrect cation levels, could result in Quality Control failures, incorrect results reporting or delay to results.

RISK TO HEALTH
Oxoid Mueller Hinton Broth, CM0405B is made available as an antimicrobial susceptibility testing medium.

From a clinical perspective we believe the risk is moderate, primarily due to the potential for delays in reporting antimicrobial susceptibility results.

Not all antimicrobial sensitivity reactions will be affected by the atypical cation level; however, if activity is affected then this is likely to be identified during user Quality Control Out of specification QC results will lead to repeat testing with the option to utilise alternative

methodologies. is less important for therapy of individual patients so the immediate clinical risk should be considered low.

ACTIONS TO BE TAKEN

Our records indicate that you have received the above product.

Accordingly, in keeping with our Quality Policy, we request that you destroy any remaining inventory of the lots listed above and contact Customer Services or your local distributor regarding any necessary replacements. Requirement for review of reported test results should be determined by the appropriate technical expert.

The Dutch Health Care Inspectorate has been informed of this Field Safety Corrective Action.

This notice needs to be passed on to all who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. If you have any questions, please contact our Technical Support Department on +31 (0) 20 4106500, or at oxoidNL@thermofisher.com.

You should complete the accompanying Acknowledgment Form in regard to inventory you have received and/or which is still in stock.

We appreciate your immediate attention to this matter and apologise for any inconvenience this may have caused.

Yours sincerely,

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