

14th February 2018

URGENT FIELD SAFETY NOTICE

**ThermoScientific™ Oxoid™ Mueller Hinton Broth, CM0405B, Batch 1765821,
D.O.M. 29/10/2015**

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 Lot 1765821 has incorrect Magnesium cation information detailed on the product label.

Lot: 1765821

Current values: 2.293 mg Mg++ per litre

Correct values: 4.883 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.

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 lot 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 Medicines and Healthcare products Regulatory Agency (MHRA) 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 +44 (0)1256 694238, or at microbiology.techsupport.uk@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,



James H Filer
Vice President, Quality and Regulatory, MBD