Rev 1: September 2018
FSN Ref: FSN-2021-008 FSCA Ref: FSN-2021-008

Date: 18-AUG-2021

Urgent Field Safety Notice (FSN)
ThermoScientific™ Oxoid™ Egg Yolk Emulsion SR0047C

For Attention of*: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)*
E.mail : mbd.vigilance@thermofisher.com Telephone: +44(0) 1256 841144 Fax: +44(0) 1256 479525

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Culture Media Supplement
1.	2. Commercial name(s)
	ThermoScientific™ Oxoid™ Egg Yolk Emulsion
1.	3. Unique Device Identifier(s) (UDI-DI)
	5032384013913
1.	4. Primary clinical purpose of device(s)*
	ThermoScientific™ Oxoid™ Egg Yolk Emulsion is a stabilised emulsion of egg yolk for use in culture media. It may be added directly to nutrient media for the identification of *Clostridium, Bacillus* and *Staphylococcus* species by their lipase activity.
1.	5. Device Model/Catalogue/part number(s)*
	SR0047C
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	3281762
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	An internal investigation by Oxoid Limited, part of Thermo Fisher Scientific, has confirmed that the standard appearance of the emulsion is an orange/ yellow colour, the batch subjected to this FSN indicates a white/cream colour. The pH of the emulsion is approximately 5.5. where the specification pH is 6.0-6.5. The pale colouration of the emulsion is resulting in pale colouration and a visible surface film of finished products when used in conjunction with typical culture media formulations. Alongside the visual defects highlighted several microbiological parameters are not meeting our accepted release criteria: • ThermoScientific™ Bacillus cereus Selective Agar Base (CM0617) - *Pseudomonas* is not inhibited • ThermoScientific™ MYP Agar (CM0929) – *Bacillus sp* growth is restricted • ThermoScientific™ Blood agar base (CM0055) - *Staphylococcus aureus* does not produce zones
2.	2. Hazard giving rise to the FSCA*
	Continued use of these lots could produce incorrect reactions and reduced colony size.
	3. Probability of problem arising

2.	The batch appearance is significantly different from the described specification and other batches, the issue is likely to be noticed before opening and the batch would not be used for testing.
2.	4. Predicted risk to patient/users
	There should be no immediate or long-term consequences from use of this product. The use of this product provides only additional information on the identity of a clinical species and is not the only determination of identity.
2.	5. Further information to help characterise the problem
	The pale colour should be noticed by users, and the material does not use for clinical testing. If the emulsion is not used very early in its shelf life (when performance is satisfactory), standard quality control strain will not perform as expected.
2.	6. Background on Issue
	This issue is currently suspected to be caused by variability in the raw materials used to manufacture the impacted batch.
2.	7. Other information relevant to FSCA
	N/A

3. Type of Action to mitigate the Risk*		
3.	1. **Action To Be Taken by the User*** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification/inspection ☒ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None	
3.	2. By when should the action be completed?	Without undue delay
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes We request that the requirement for review of reported test results should be determined by the appropriate technical expert.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	Without undue delay
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? Choose an item. Choose an item. N/A	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Thermo Fisher Scientific
	b. Address	Wade Road, Basingstoke, Hampshire RG24 8PW
	c. Website address	www.thermofisher.com/microbiology
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Acknowledgement form
4.	10. Name	
	Signature	

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*