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Class 1 Device Recall 10 NBF



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Class 1 Recall 10 NBF



Date Posted	October 09, 2014
Recall Status¹	Open
Recall Number	Z-0014-2015
Recall Event ID	69276²³
Product Classification	Fixative, Formalin-Containing ²⁴ - Product Code LDY ²⁵
Product	Richard-Allan Scientific 10% Neutral Buffered Formalin. Product Usage: 10% NBF is used to store and fixate tissue prior to grossing and histological examination. It is a primary fixative that prevents autolysis (degradation) of tissue.
Code Information	Product Code: LC-0060 Lot Number: 300445
Recalling Firm/ Manufacturer	Richard-Allan Scientific Company 4481 Campus Dr Kalamazoo, Michigan 49008-2590
For Additional Information Contact	Sarah Rickert 616-385-4466
Manufacturer Reason for Recall	The affected lots could have NBF concentrations that are lower or higher than the desired specifications.
FDA Determined Cause²	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Mix-Up of Materials/Components
Action	The firm issued an "URGENT MEDICAL DEVICE RECALL" letter to all affected customers. The notification identified the affected products, reason for voluntary recall, risk to health, actions to be taken, and instructions to complete the attached Acknowledgement Form. For questions, contact Sarah Rickert at 269-544-5628 or sarah.rickert@themofisher.com.
Quantity in Commerce	80 cases
Distribution	Worldwide Distribution-USA (nationwide) including the states of PA, IL, CA, TX, GA, WA, MA, KY, OH, NY, VA, NC, IN, NJ, MN, UT, HI, FL, KS, TN, MO, MI, MD, LA, NM, DE, CO, WV, OR, WI, AZ, SC, IA, and NE and the country of Canada.
Total Product Life Cycle	TPLC Device Report ²⁶

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55²⁷](#)

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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**Class 1 Recall
10 NBF**



Date Posted	October 09, 2014
Recall Status¹	Open
Recall Number	Z-0016-2015
Recall Event ID	<u>69276</u> ²³
Product Classification	Fixative, Formalin-Containing ²⁴ - Product Code LDY ²⁵
Product	Richard-Allan Scientific 10% Neutral Buffered Formalin. Product Usage: 10% NBF is used to store and fixate tissue prior to grossing and histological examination. It is a primary fixative that prevents autolysis (degradation) of tissue.
Code Information	Product Code: 51401 Lot Number: 300649
Recalling Firm/ Manufacturer	Richard-Allan Scientific Company 4481 Campus Dr Kalamazoo, Michigan 49008-2590
For Additional Information Contact	Sarah Rickert 616-385-4466
Manufacturer Reason for Recall	The affected lots could have NBF concentrations that are lower or higher than the desired specifications.
FDA Determined Cause²	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Mix-Up of Materials/Components
Action	The firm issued an "URGENT MEDICAL DEVICE RECALL" letter to all affected customers. The notification identified the affected products, reason for voluntary recall, risk to health, actions to be taken, and instructions to complete the attached Acknowledgement Form. For questions, contact Sarah Rickert at 269-544-5628 or sarah.rickert@thermofisher.com.
Quantity in Commerce	199 cases
Distribution	Worldwide Distribution-USA (nationwide) including the states of PA, IL, CA, TX, GA, WA, MA, KY, OH, NY, VA, NC, IN, NJ, MN, UT, HI, FL, KS, TN, MO, MI, MD, LA, NM, DE, CO, WV, OR, WI, AZ, SC, IA, and NE and the country of Canada.
Total Product Life Cycle	TPLC Device Report ²⁶

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)²⁷

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