

November 15, 2024

Ref #: FA-2024-035

**URGENT: PRODUCT FIELD ACTION**

**RE: O&M Halyard, Inc. Product Field Action – HALYARD\* PUREZERO\* Limon\* Nitrile Exam Gloves (Lot #, SM4144ZZZ, Lot # SM4145ZZZ and Lot # SM4146ZZZ)**

Dear Valued Customer,

A Product Field Action is being initiated by O&M Halyard, Inc. related to the HALYARD\* PUREZERO\* Limon\* Nitrile Exam Gloves (codes 48751 -48753). This Field Action is related to not meeting the minimum breakthrough time of 30 minutes for n-Heptane required for Type B certification per ISO 374-1:2016+A1:2018 and EN 16523-1:2015+A1:2018. While O&M Halyard, Inc. has received zero complaints or reports of adverse events that would indicate a real-world concern, O&M Halyard, Inc. is issuing this voluntary Field Action.

**EVENT DETAILS:**

This action affects the product codes and lot numbers identified in the table below. The lots were distributed between August 2024 and October 2024. O&M Halyard, Inc. records indicate you have received **HALYARD\* PUREZERO\* Limon\* Nitrile Exam Gloves** from one of these specific lots that is associated with this action as listed below. The issue surrounding this Field Action is related to not meeting the minimum breakthrough time of 30 minutes for n-Heptane required for Type B certification per ISO 374-1 and EN 16523-1:2015+A1:2018. No other codes or lots of exam gloves are impacted in the Field Action.

**Affected Products:**

Product Name	Alternative Code	Code	Lot Number
HALYARD* PUREZERO* Limon* Nitrile Exam Gloves	LFS311SM	48751	SM4145ZZZ
HALYARD* PUREZERO* Limon* Nitrile Exam Gloves	LFS311MD	48752	SM4145ZZZ
HALYARD* PUREZERO* Limon* Nitrile Exam Gloves	LFS311MD	48752	SM4144ZZZ
HALYARD* PUREZERO* Limon* Nitrile Exam Gloves	LFS311LG	48753	SM4146ZZZ

**Risk to Health:** The associated risk with the use of these exam gloves is potential skin/tissue damage or irritation.

**Actions to Take:**

Please review your inventory, and segregate and quarantine all affected product. All other codes and lots of this product are NOT impacted by this Field Action.

**Distributors:**

1. REVIEW your inventory for the affected **product code(s)** and **specific lot number(s)**.
2. DESTROY or DISCARD the product per the facility's standard disposal procedure.
3. COMMUNICATE this voluntary Field Action to your staff to ensure awareness of it.
4. If any of the affected lot(s) identified above were further distributed, please ensure all end-users are appropriately notified of this Field Action and maintain records of effectiveness.
5. Any adverse events associated with the use of the affected product should be reported to [complaints@owens-minor.com](mailto:complaints@owens-minor.com).

6. RETURN the completed Field Action Response Form to [OMRA\\_RECALLS@owens-minor.com](mailto:OMRA_RECALLS@owens-minor.com) as soon as possible even if you have no current product inventory.

If you have any questions, please email [OMRA\\_RECALLS@owens-minor.com](mailto:OMRA_RECALLS@owens-minor.com) using the Event # FA-2024-035 in the header of the response. This will ensure prompt response by the O&M Halyard, Inc, team.

Thank you,

Caitlin Senter, MS, RAC  
O&M Halyard, Inc.

Enclosures:  
Field Action Response Form