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Change Notification Letter

Date Issued: September 8, 2020

Change Notification Number: 2340

Subject: Pall Biotech Kleenpak® sterile connector and Kleenpak Presto sterile connector membrane peel strip material change

Effective Date: October 2020

Dear Valued Customer,

This letter serves as formal notification of changes that may affect products or services purchased by your organization.

Scope of Notification: Pall Biotech Kleenpak sterile connector and Kleenpak Presto sterile connector membrane peel strip material change. Affected products stated in the Pall Customer Notification Letter (attached).

Description of Change: Change is due to the impending environmental restriction of a compound used in the manufacturing of the membrane peel strip in Kleenpak sterile connectors and Kleenpak Presto sterile connectors. To minimize the impact of the change, the existing polyethersulfone membrane has been retained and the surface chemistry that conveys hydrophobicity replaced with a shorter chain perfluorocarbon.

Important Points of Note:

- Connector membrane peel strip material change ensures compliance with the European Commission Persistent Organic Pollutants (POPs) Regulation 2019 / 2021.
- The previously proposed REACH restriction has been removed.
- Parts manufactured at the Pall Newquay UK and Pall Ilfracombe UK will be impacted.
- A full validation package is available upon request. More iterations / updates available when completed.
- Sample parts are being tested as a part of our sterility program protocol.
- Connector membrane peel strip maintains sterility of the connector post sterilization by irradiation or autoclaving.
- Parts will retain the same part number.
- Impacted Pall products part numbers listed in Pall Notification.

Should you have any questions regarding this notice, please contact us at compliance@newageindustries.com. Other change notifications and details about our Change Notification Policy can be found on our website at <http://www.advantapure.com/change-notifications.htm>.

Thank you for your continued support of NewAge Industries AdvantaPure®.



Gregg Donovan
AdvantaPure Product Manager