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November 30, 2021

Re: Update to DCR 2331

Original Notification Date: July 21, 2020

1st Update: September 2, 2020

2nd Update: March 9, 2021

3rd Update: August 5, 2021

Subject:

NewAge Industries AdvantaPure® Tubing and Hose Manufacturing Location Expansion

Change Description:

This letter serves as an update to the information shared previously in the above-mentioned communications. The following project updates have been made to the 97,000 ft² AdvantaSil® and AdvantaFlex® facility expansion located at 364 Valley Rd., Warrington, PA 18976, with an effort to continually improve our product quality and lead times. Upon completion of two separate implementation phases, 22,000ft² of ISO 14644 certified cleanroom extrusion space will become operational. The project is broken into two (2) phases with a total of seven (7) unique extrusion suites.

Affected Product Part Numbers:

Part Series Affected of Platinum Cured Silicone	A700, A701, A702, A704, A705, A710 (Liner), A714 (Liner), A718 (Liner), A719 (Liner), CA700, CA701, CA702, CA703, CA704, CA705, CA709, CA710 (Liner), CA714 (Liner), CA718 (Liner), CA719 (Liner), CA131, CA132, CA133, CA135, CA200, CA220, CA731, CA732, CA733, CA734, CA735, CA736, CA737, CA738, A892, CHA710, CSA131, CSA132, CSA133, CSA135, CSA731, CSA732, CSA735
Part Series Affected of AdvantaFlex TPE	A750, A760, A761, A762, A765, A767, CA750, CA761, CA762, CA763, CA764, CA765, CA767, CA768, CSA761, CSA762, CSA765, CA892

Change Impact Assessment:

Phase One (1)

The new 8,400 ft² manufacturing facility of ISO 7 & 8 certified cleanroom space is to better serve NewAge Industries AdvantaPure® customers, further reducing the risk of contamination and environmental variability. The new spaces consist of three (3) extrusion suites; unreinforced, reinforced platinum silicone and TPE tubing.

The additional location will add cleanroom product extrusion capacity, assuring redundancy and security of supply. There is no impact on the form, fit or function to the products affected by this change and no changes to the manufacturing process, testing methods, or product release criteria.

- Construction of the new manufacturing facility is completed.
- The extrusion lines have been placed and are undergoing the Installation Qualification (IQ).
- The Equipment Operational and Performance Qualification (PQ) are expected to be completed by the end of December 2021.
- The three (3) extrusion suites are expected to be fully approved by the end of February 2022.
- Upon completion of Phase 1 validation activities, an executive summary report will be available and will discuss the results of each qualification stage and subsequent product testing.

Implementation Date:

Based on the planning projections, samples of the part numbers produced at the new NewAge Industries AdvantaPure manufacturing location are expected to be available for customer testing by Q1 2022.

For any change approval needs, please reach out to compliance@newageindustries.com to fulfill your requests. The BPOG/RX360 audit is anticipated to be completed in Q1 2022. Upon completion, the audit report of the new site can be licensed through the [joint audit program](#).

Next Steps:

Additional updates will be provided on the subsequent Phases of the new manufacturing location. Please take this opportunity to contact our Customer Service Representative Team at (215) 526-2151 or email compliance@newageindustries.com should you have any questions or concerns.

Thank you for your continued support of NewAge Industries AdvantaPure.



Paula Martinelli
Life Sciences Product Manager



Mary Marcus
Executive Director of Quality