



145 James Way, Southampton, PA 18966  
215-526-2300 • Fax: 215-526-2191  
info@newageindustries.com • www.newageindustries.com

October 3, 2022

**Re: Update to DCR-2331 – Phase II Additional Silicone Extrusion Lines**

Original Notification Date: July 21, 2020

1<sup>st</sup> Update: September 2, 2020

2<sup>nd</sup> Update: March 9, 2021

3<sup>rd</sup> Update: August 5, 2021

4<sup>th</sup> Update: November 30, 2021

5<sup>th</sup> Update: February 8, 2022

6<sup>th</sup> Update: July 18, 2022

**Subject:** NewAge Industries AdvantaPure® Tubing and Hose Manufacturing Location Expansion –  
**Conclusion of PHASE II**

**Change Description:**

This letter serves to notify our customers about the qualification of an additional extrusion line for AdvantaSil® platinum cured silicone tubing (APST). NewAge® Industries has completed the IQ/OQ/PQ for this additional extrusion line.

**Affected Product Part Numbers**

AdvantaSil Silicone tubing				
Material	Description	Catalog Part Number	Product Family Number	Raw Material Number
Platinum Cured Silicone	AdvantaSil Unreinforced Platinum-Cured Silicone Tubing	APST-xxxx-xxxx	A700	NI201

**Change Impact Assessment:**

NewAge Industries has completed the qualification which includes the installation and validation of 1 (one) additional extrusion line for APST silicone tubing. The additional line was placed in a previously certified ISO 7 cleanroom.

The ISO 7 suite was built and designed to adequately handle the demands of 2 (two) production lines in the same suite. Subsequently, the room was confirmed and requalified in an at-rest and operational state to ensure the highest quality standards will continue to be met.

Please, refer to the previous communication letter ([DCR-2331 Feb 2022 Communication](#)) to review the provided change assessment applicable to the first and second phase of the expansion.

**Implementation Date:**

The new site validation summary is available upon request as well as the associated equipment and product-specific validation activities. With the data collected, product performance has been verified to be comparable as a result of this validation process.

As of September 16, 2022 the APST part number outlined above have been released for distribution. Customers will be given the appropriate support to review the validation data for the part numbers affected by this change.

With the addition of the line, the second phase of this expansion project is considered complete. Any future changes will be accompanied by a new change notification.

**Next Steps:**

Please take this opportunity to contact our Customer Service Representative Team at (215) 526-2151 or email [compliance@newageindustries.com](mailto:compliance@newageindustries.com) should you have any questions or concerns.

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

Sincerely,



Paula Martinelli  
Life Sciences Product Manager



Faisal Haque  
Director of Quality