

## Pharmaceutical Products/ Melamine Content Certification

The following products are not manufactured utilizing melamine and nothing in the raw materials, process or chemistry of these polymers generates melamine as residuals, by-products, or from side reactions. As explained in the FDA guidance document, " *Pharmaceutical Components at Risk for Melamine Contamination*," the term *at-risk components* (for melamine contamination) include those ingredients or raw materials that rely on a test for nitrogen content for their identity or purity or strength and that contain nitrogen in amounts greater than 2.5%."

Test for nitrogen content is not part of testing conducted for their identity or purity or strength and they are not considered at-risk components for melamine contamination. Consequently, melamine is neither expected nor tested for in these products. We do not routinely analyze purchased raw materials or products we manufacture for melamine; however melamine is not expected to be present in the products at 0.1 wt. % or greater, either intentionally or as an impurity, based on information received from our suppliers and knowledge of our manufacturing processes.

Carbopol<sup>®</sup> 71G NF polymer

Carbopol<sup>®</sup> 934 NF polymer

Carbopol<sup>®</sup> 934P NF polymer

Carbopol<sup>®</sup> 940 NF polymer

Carbopol<sup>®</sup> 941 NF polymer

Carbopol<sup>®</sup> 971P NF polymer

Carbopol<sup>®</sup> 974P NF polymer

Carbopol<sup>®</sup> 980 NF polymer

Carbopol<sup>®</sup> 981 NF polymer

Carbopol<sup>®</sup> 1342 NF polymer

Carbopol<sup>®</sup> 5984 EP polymer

Carbopol<sup>®</sup> ETD 2020 NF polymer

Carbopol<sup>®</sup> Ultrez 10 NF polymer

Noveon<sup>®</sup> AA-1 Polycarbophil, USP

Pemulen<sup>™</sup> TR-1 NF polymer

Pemulen<sup>™</sup> TR-2 NF polymer

SIGNED:

NAME:



TITLE:

Director, Regulatory Strategy & Policy  
Personal, Home and Health Care

DATE:

September 2018

**Lubrizol Advanced Materials, Inc. / 9911 Brecksville Road, Cleveland, Ohio 44141-3247 / TEL: 800.379.5389 or 216.447.5000**

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