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® 71G NF polymer
- Carbopol® 793 NF polymer
- Carbopol® 934P NF polymer
- Carbopol® 940 NF polymer
- Carbopol® 941 NF polymer
- Carbopol® 971P NF polymer
- Carbopol® 974P NF polymer
- Carbopol® 980 NF polymer
- Carbopol® 981 NF polymer
- Carbopol® 1342 NF polymer
- Carbopol® 5984 EP polymer
- Carbopol® 1540 NF polymer
- Carbopol® Ultrez 10 NF polymer
- Noveon® AA-1 Polycarbophil, USP
- Pemulen™ TR-1 NF polymer
- Pemulen™ TR-2 NF polymer

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PERSONAL, HOME AND HEALTH CARE
DATE: September 2018