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Current Avantor™ Performance Materials Responses to FDA Guidance "Pharmaceutical Components at Risk for Melamine Contamination"

This is a general notice to inform concerned customers of the steps Avantor™ Performance Materials is taking to address recommendations made by the US Food and Drug Administration on August 6, 2009, to assure against melamine contamination in pharmaceutical components.

1. Avantor Performance Materials has identified the at-risk products we produce and market. Avantor does not consider adulteration of these products likely for reasons stated in the comments column.

Product Name	Part Numbers	Comments
Ammonium Chloride	Macron Fine Chemicals™ 3364	Produced in the United States from inorganic raw materials. Addition of melamine to the product has no commercial advantage. Historical supplier to Avantor and is part of Avantor supplier assurance program.
Ammonium Sulfate	J. T. Baker® 0797, 0798, 4628	Product produced in the United States by Avantor from inorganic raw materials. Addition of melamine to the product has no commercial advantage. Avantor maintains control over product through authorized distributors and direct sales.
Lactose	Macron Fine Chemicals™ 6270; J. T. Baker® 2249, 2250	Produced in the United States from dairy products of domestic origin. Addition of melamine to the product has no commercial advantage. Manufacturer assured Avantor of integrity of their supply chain. GMP product. Historical supplier to Avantor and is part of Avantor supplier assurance program.

Product Name	Part Numbers	Comments
Urea	Macron Fine Chemicals™ 7816, 8642; J. T. Baker® 4202, 4206, 4208	Produced in United States exclusively for Avantor from inorganic raw materials. Historical supplier to Avantor and is part of Avantor supplier assurance program. Additionally, current monograph tests for melting point and alcohol insoluble matter nonspecifically address economically motivated melamine adulteration. Presence of melamine negatively impacts these tests. Economic adulteration is of questionable value as urea is a raw material in the production of melamine.
MHC-300G (contains crospovidone)	JT Baker® 4489	Product manufactured by Avantor. Crospovidone is from domestic production. Crospovidone producer is GMP and product is USP Verified®. Supplier is part of Avantor supplier assurance program Supplier has tested for the presence of melamine with none detected by the recommended FDA HPLC-MS method.
Calcium Pantothenate	JT Baker® 1443	Product manufactured under GMP in the United Kingdom. Current USP monograph replaced total nitrogen testing with substance specific HPLC testing. Change in testing makes economic adulteration with melamine detectable and makes melamine an impurity that would adversely impact the testing.

2. Other Avantor Performance Materials products do not bear a likely or significant risk of melamine adulteration due to a number of factors such as, but not limited to: type and source of raw materials, type of product, control of product and process, and supplier management.
3. Avantor has examined our products marketed under GMP for pharmaceutical use. Avantor products designated for other markets (e.g., general reagents, semiconductor, etc.) were not considered since they are produced and marketed for non-pharmaceutical use.
4. Although Avantor does not have the current capability to perform testing of the type referenced by FDA in their guidance, we are capable of developing and validating methodology to test those at-risk products that cannot be assured by other means. Currently, Avantor does not plan to directly test for melamine in our products. The

primary assurance against melamine adulteration is control of our supply chain and the Avantor Supplier Assurance Program. Any products labeled as Avantor materials have either been packaged under the direct control of Avantor, or by a qualified Avantor subcontractor. After Avantor material is in its final commercial packaging, no further direct handling of the substance (i.e., subdivision, repacking) occurs by any approved distribution agents of Avantor products.

5. FDA requested USP to develop testing to detect melamine adulteration, and Avantor plans to comply with any USP requirements that arise from that request.

6. Under no circumstances does Avantor or any of Avantor's qualified suppliers or distributors intentionally add melamine to Avantor labeled products. Addition of melamine is considered product adulteration and is both illegal and unethical.

Please note that this general notice will be updated periodically and provides information on Avantor's current activities addressing potential melamine contamination. At this time, Avantor does not plan on providing additional information by way of product Certificate of Analysis or revised Product Data Sheets.

If further information is required, please contact your Avantor Technical Services Representative.

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