

Avantor
Technical Service Department
600 Hamilton St.
Allentown, PA 18101
1 855 282 6867
Technical.Service@avantorsciences.com

Date: July 15, 2022 (Revision 13)

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

This is a general notice to inform concerned customers of the steps Avantor™ 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.

This information applies to J.T. Baker® and Macron Fine Chemicals™ GMP products released from our U.S., India and Poland sites.

1. Avantor 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 Sulfate	J. T. Baker®, 0798, 4628, 3523	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	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.
Urea	Macron Fine Chemicals™ 7816, 8642; J. T. Baker® 4202, 4203, 4205, 4206, 4208, NY22	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.

Product Name	Part	Comments
MHC-300G (contains crosppovidone)	JT Baker® 4489	Product manufactured by Avantor. Crosppovidone is from domestic production. Crosppovidone 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.

- Other Avantor 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.
- 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.
- 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.
- FDA requested USP to develop testing to detect melamine adulteration, and Avantor plans to comply with any USP requirements that arise from that request.
- 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 you have any questions or require additional information, please contact Technical Services.

Prepared by the Avantor
Technical Service Department
Toll free 1 855 282 6867, select option 5

Rev. 12; January 12, 2021 - Added statement identifying brand and release site of products addressed.
Removed delisted products 3364, 0797, 6270. Added codes 3523, 4203, 4205.
Rev. 13 July 11, 2022 – Added Poland site. Added code NY22. Removed duplicated Urea information.

While the above information is provided in good faith and believed to be accurate as of the date provided, Avantor makes no representations or warranties as to the accuracy or completeness of such information. All Avantor products are subject to Avantor's terms and conditions of sale including the limitations of liability contained therein and any contrary terms and conditions are expressly rejected. As Avantor has no control over purchasers' uses of its products, Avantor expressly disclaims all liability with respect to same.