

## **Avantor**

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## Expiration Assignment for J.T. Baker® and Macron Fine Chemical™ Products

Based upon the results of stability studies, research data, or technical product information, Expiration Dates for Avantor™ J.T. Baker® and Macron Fine Chemical™ products are established for those chemicals with known limited stability. Retest Dates are established for those chemicals that are considered inherently stable in which no data exist that shows product failure.

Expiration or retest dates are typically assigned in the following situations for batch material manufactured on or after April 30, 2012\*:

- 1. It is an FDA regulated product and stability data indicates it maintains its stability profile for the life of the stability study (typically 5 years); a Retest Date of 5 years is assigned.
- 2. It is an FDA regulated product and stability data indicates it will NOT maintain its stability profile for less than 5 years; an Expiration Date is assigned.
- 3. It is a non-regulated, non-GMP manufactured product and historical data indicates it maintains its product specifications; a Retest Date is assigned. If information indicates it will have a limited stability, an Expiration Date is assigned.
- 4. Specific products or product lines may be assigned retest dates at the request of Marketing for specific customer groups. Such assignment may represent a time period equal to or shorter than the known stability profile indicates, but not for a longer period.
- 5. Stability studies are actively ongoing and under assessment based on the product's Avantor's Management of Change (MOC) category and regulatory requirements. Should a change to the expiration or retest period of a product be indicated, notification will be sent to customers of MOC code HR, R, and RL, who have a registered email address for change notification with Avantor.

Expiration and retest dates are valid only under the storage and handling conditions noted on the label and/or Certificate of Analysis in its original, unopened container. Generally, products should be stored and handled under the conditions noted on the label and should not be exposed to temperature or humidity extremes.

\*For products that do not have an expiration/use-before date or a retest date, these products can generally be considered stable for at least 5 years from date of release in their original, unopened container.

Once the product container is opened, the shelf life of the product is dependent on how the product is stored and handled within your facility. If you question the quality of a product that carries no expiration date, a product that exceeds its retest date, or a product where the container has been previously opened, product performance capability is best determined by retesting the product against the original Quality Control tests and specifications provided on the Certificate of Analysis.

For additional information about Avantor's Management of Change (MOC) process, please refer to <a href="https://www.avantorsciences.com/pages/en/management-of-change">https://www.avantorsciences.com/pages/en/management-of-change</a>.



If you have any questions, require additional information, or wish to register for change notification, please contact Technical Service.

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## Revision History

Rev. 17; January 6, 2022: Start new format. Added bullet 5 and information on MOC program. Minor edits.

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