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Expiration Assignment

Normally our products do not require expiration or retest dates on the label or Certificate of Analysis due to their inherent stability. These products can generally be considered stable for at least five (5) years from the date of release in their original, unopened container.

Expiration or retest dates are assigned in the following situations:

- 1) It is an FDA regulated product and stability data indicates it will NOT maintain its stability profile for at least two (2) years.
 - Note: If an FDA regulated product is determined to be stable for two or more years, it will typically NOT carry an expiration date or retest date. However, we continue to conduct stability studies on these products for up to five years. It is the policy of Avantor Performance Materials, Inc. to enclose a "Use-Before" date on both the product label and Certificate of Analysis for all GMP products that exhibit an inherent instability of less than two years. If the stability of the product surpasses two years or more, the product is considered stable and typically no expiration date is assigned.
- 2) It is not an FDA regulated product and we have experience or data indicating a limited shelf-life, or at the request of marketing.

Expiration and retest dates are valid only under the storage and handling conditions noted on the label and/or Certificate of Analysis. Generally, products should be stored and handled under the conditions noted on the label and should not be exposed to temperature or humidity extremes. Once the product container is opened, the shelf-life of the product is dependent on how the product is stored and handled.

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, we recommend testing the product for fitness for use in your particular application against key parameters.

Prepared by: Technical Service Dept.

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