Re: Lactic Acid Product Code 0200 Optical Rotation – USP Monograph
Date: September 30, 2016

Avantor™ Performance Materials L-Lactic Acid (product code 0200) is a naturally derived product with a levorotatory optical rotation. According to the USP lactic acid monograph Definition section, compliant lactic acid may be either naturally obtained by fermentation (levorotatory) or produced synthetically (racemic). The following are the pertinent sections pertaining to optical rotation from the USP monograph.

DEFINITION

- Lactic Acid is a mixture of lactic acid (C3H6O3) and lactic acid lactate (C6H10O5), equivalent to a total of NLT 88.0% and NMT 92.0%, by weight, of lactic acid (C3H6O3). It is obtained by the lactic fermentation of sugars or is prepared synthetically. **Lactic Acid obtained by fermentation of sugars is levorotatory, whereas that prepared synthetically is racemic.**
  [Note—Lactic Acid prepared by fermentation becomes dextrorotatory on dilution, which hydrolyzes l-(−)-lactic acid lactate to l-(+)-lactic acid.]
- **Optical Rotation, Angular Rotation (781A):** −0.05° to +0.05° for racemic Lactic Acid
- **Labeling:** Label it to indicate whether it is levorotatory or racemic.

Although compliant lactic acid may be either levorotatory or racemic, the monograph only contains a requirement for the racemic form. Since the Avantor product is levorotatory, the optical rotation requirement for racemic lactic acid cannot be applied and so does not constitute a test for compliance for product 0200. The product label and Certificate of Analysis indicate the lactic acid as levorotatory in accordance with the USP labeling requirement.

We hope this information is useful. If you require any additional information, please contact Avantor Technical Services.