National Institute of Standards & Technology

Certificate of Analysis

Standard Reference Material® 3251

Serenoa repens Extract

This Standard Reference Material (SRM) is intended primarily for use in validating analytical methods for the determination of phytosterols, fatty acids, β-carotene, and γ-tocopherol in extracts of *Serenoa repens* (saw palmetto) and similar matrices. This SRM can also be used for quality assurance when assigning values to in-house control materials. A unit of SRM 3251 consists of five ampoules, each containing approximately 1 mL of saw palmetto extract.

The development of SRM 3251 was a collaboration among the National Institute of Standards and Technology (NIST), the National Institutes of Health, Office of Dietary Supplements (NIH ODS), and the Food and Drug Administration, Center for Drug Evaluation and Research (FDA CDER).

Certified Concentration Values: A NIST certified value is a value for which NIST has the highest confidence in its accuracy in that all known or suspected sources of bias have been investigated or taken into account [1]. The certified concentration values of selected phytosterols, fatty acids, total β-carotene, and γ-tocopherol are provided in Tables 1 through 3. Values for fatty acids, β-carotene, and γ-tocopherol were derived from the combination of results provided by NIST using two independent methods. Values for phytosterols were derived from the combination of results provided by NIST using two independent methods and by an AOAC collaborative study. The certified values in this material are the equally weighted means of the individual sets of results; the associated uncertainties are expanded uncertainties at the 95 % level of confidence [2,3]. Values are reported on an as-received basis in mass fraction units [4].

Reference Concentration Values: Reference values are noncertified values that are the best estimate of the true values based on available data; however, the values do not meet the NIST criteria for certification [1] and are provided with associated uncertainties that may reflect only measurement reproducibility, may not include all sources of uncertainty, or may reflect a lack of sufficient statistical agreement among multiple analytical methods. Reference concentration values for cycloartenol, total fatty acids (as triglycerides), free fatty acids, β-carotene isomers, and δ-tocopherol are provided in Tables 4 through 7.

Information Concentration Values: An information value is a value that may be of interest to the SRM user, but insufficient information is available to assess the uncertainty associated with the value therefore no uncertainty is provided [1]. Information concentration values for two phytosterols are provided in Table 8. These concentrations are listed as information values because they were determined by a single analytical method (gas chromatography with flame ionization detection) and their identities could not be confirmed by mass spectrometry.

Expiration of Value Assignment: The certification of **SRM 3251** is valid, within the measurement uncertainty specified, until **30 August 2019**, provided the SRM is handled and stored in accordance with the instructions given in this certificate. (See "Instructions for Use"). The certification is nullified if the SRM is damaged, contaminated, or otherwise modified.

Maintenance of SRM Value Assignment: NIST will monitor this SRM over the period of its value assignment. If substantive technical changes occur that affect the value assignment before the expiration of this certificate, NIST will notify the purchaser. Registration (see attached sheet) will facilitate notification.

Coordination of the technical measurements leading to the certification of this SRM was performed by L.C. Sander, and S.A. Wise of the NIST Chemical Sciences Division, and K.E. Sharpless of NIST

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Certificate Issue Date: 04 April 2014
Certificate Revision History on Page 8

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