

Ginkgo biloba Dietary Supplement Standard Reference Materials

NIST is working in collaboration with the National Institutes of Health Office of Dietary Supplements (NIH-ODS), and Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) and Center for Food Safety and Applied Nutrition (CFSAN) to develop dietary supplement Standard Reference Materials (SRMs) to support these needs. A suite of five ephedra-containing SRMs have recently been issued. Ginkgo-containing reference materials will be the next SRMs to be issued as part of this program.

**L. C. Sander, K. E. Sharpless, and
S. A. Wise (Div. 839)**

The enactment of the Dietary Supplement Health and Education Act (DSHEA) in 1994 by the U. S. Congress has promoted growth in the nutritional supplement industry, due in part to the way in which dietary supplements are regulated. DSHEA provides a legal definition of dietary supplements that classifies these materials separately from food additives and pharmaceutical drugs. Requirements for product labeling are less stringent than for drug substances, and the burden of proof for the safety of dietary supplements is placed on the FDA. Reference materials are needed for use in method validation and as controls to support the analysis of dietary supplements and related botanical materials. Potential applications include: 1) verification of product label claims; 2) quality assurance in product manufacturing; and 3) support of measurements associated with clinical trials.

A suite of three ginkgo-containing SRMs has been developed: SRM 3246 *Ginkgo biloba* (Leaves), SRM 3247 *Ginkgo biloba* Extract, and SRM 3248 Ginkgo-Containing Tablets, representing a variety of natural, extracted, and processed sample matrices that provide different analytical challenges. These three materials will have certified values for ginkgolides, bilobalide, flavonoid aglycones, and selected toxic trace elements. The concentrations of these constituents have been determined by multiple independent methods with measurements performed by NIST and collaborating laboratories. The methods utilized different sample extraction and cleanup steps in addition to different instrumental analytical techniques and approaches to quantification. In addition to the three individual SRMs, all three ginkgo-containing SRMs will be available packaged together as SRM 3249.

This suite of *Ginkgo biloba* SRMs represents the second in a series of dietary supplement SRMs to be offered by NIST with certified values for organic constituents and selected trace elements.

These materials are provided primarily for use in method development and as control materials to support analytical methods for the determination of these constituents. The SRM suites will assist manufacturers of dietary supplements to characterize raw materials, to prevent the use of materials that are contaminated or adulterated. In addition, the SRMs will assist self-assessment of consistency and quality in finished products, and to provide a foundation to which accuracy of label information can be linked. The goal of this ongoing effort is to provide tools to the dietary supplement industry and measurement communities that will lead to improved quality of dietary supplements, and ultimately reduce public health risks that could potentially be associated with these products.



A photograph of Ginkgo biloba leaves such as those used in the production of SRM 3246.

SRM 3249 is the suite of Ginkgo biloba SRMs:

***SRM 3246 Ginkgo biloba (Leaves)
SRM 3247 Ginkgo biloba Extract
SRM 3248 Ginkgo-Containing Tablets***