USDA Dietary Supplement Ingredient Database Release 4.1

Green tea (single ingredient) dietary supplement study

Research Summary and Results

Prepared by

Dietary Supplement Ingredient Database Team

Originally published online in August 2017

U.S. Department of Agriculture
Agricultural Research Service
Beltsville Human Nutrition Research Center
Methods and Application of Food Composition Laboratory
307C Center Road
Beltsville, Maryland 20705

Web address: https//dsid.usda.nih.gov

1. Introduction

The Dietary Supplement Ingredient Database (DSID) reports levels of ingredients in dietary supplement (DS) products based on chemical testing. The Nutrient Data Laboratory (NDL), Beltsville Human Nutrition Research Center, Agricultural Research Service (ARS), US Department of Agriculture (USDA), developed the DSID with the Office of Dietary Supplements (ODS) of the National Institutes of Health and other federal partners (National Center for Health Statistics of the Centers for Disease Control and Prevention, Food and Drug Administration, National Cancer Institute of the National Institutes of Health, and National Institute of Standards and Technology [NIST] of the Department of Commerce). ODS is the primary funder of the DSID, which builds on the well-recognized strengths of the ARS in developing databases that support assessments of intakes of nutrients from foods.

The DSID provides analytically derived estimates of the ingredient content in DS commonly sold and purchased in the US. DSID 4.0 includes estimates of ingredient content in 4 categories of DS: adult, children's and non-prescription prenatal multivitamin/mineral products (MVM) and omega-3 fatty acid DS. These mean estimates can replace label information in studies assessing the dietary intake of the US population from foods and DS.

According to the 2007-10 NHANES, 7.5% of the US population reports taking botanical DS (the 4th most common supplement type reported). Supplement labels may provide only partial information about the actual content of bioactive components in botanicals. For botanicals, current label regulations require information on the amount of each botanical or botanical extract present in a DS. However, many extracts are microencapsulated with maltodextrin or other powdered material (extracts are sprayed into a fine powder and coated) and the weight of these extracts will include the weight of the coating material. Label information on the concentration or standardization of extracts is not required. Although some companies voluntarily list information about the concentration of phytochemical constituents, many do not. For researchers to more accurately estimate the phytochemical intakes from botanicals, analytical testing is necessary.

A botanical initiative for the DSID is now underway to evaluate levels of ingredients and ingredient constituents in botanical DS. The DSID Working Group identified non-vitamin/mineral bioactive ingredients in DS for analysis and inclusion based on these criteria: public exposure (intake and sales), the availability of validated analytical methods and analytical reference materials, research interest and economic and safety concerns. The top scoring 11 ingredients from this ranking process were: CoQ10, garlic, saw palmetto, ginkgo biloba, glucosamine, ginseng, green tea catechins (EGCG and other catechins), milk thistle, echinacea, flaxseed, and turmeric (curcumin).

Green tea botanical supplements were chosen for initial study. This study tests representative and top-selling products for constituents of interest. The analytical results were compared to label claims and other label information.

2. Overview of the green tea dietary supplement study

Green tea is a botanical product that is commonly consumed and frequently studied for its health benefits and thus was chosen as the first botanical for the DSID. Since the botanical constituents in GT are also commonly found in foods and beverages, the data from these studies will complement the data on the phytochemical intake from foods.

The major goal of the pilot study was to analyze representative and top-selling products to obtain information about the content and variability of individual catechins and caffeine in GT DS. Three experienced laboratories were chosen for participation. Seven catechins (including (+)-catechin, (–)-epicatechin, (–)-epicatechingallate, (–)-epigallocatechin, (–)-epigallocatechingallate (EGCG), (–)-gallocatechin, (–)-gallocatechingallate) and caffeine were measured in a variety of green tea supplements. Three NIST green tea Standard Reference Materials® (SRMs) were sent for analysis with product samples in order to evaluate the accuracy and precision of the laboratory methods. The ingredient data for 2 lots of 32 green tea DS were combined for each product and the mean results compared to label information.

3. Sampling Plan

A sampling plan was developed to identify representative products for purchase and analysis. The scope and variety of GT DS reported in NHANES 2009-2010 and the Office of Dietary Supplement Dietary Supplement Label Database (DSLD; https://dsld.nlm.nih.gov/dsld/) were evaluated for information about GT composition, component levels and health claims. In addition, we conducted a detailed survey of GT products sold via various channels including local stores, the internet and multi-level marketing companies in 2013-14.

The first GT study was limited to products containing GT in a relatively simple matrix (products with green tea as the only ingredient or with green tea as the primary ingredient with no other botanicals), to minimize interferences for analytical results and to compare to label claims for GT constituents.

Products with a wide range of dosage forms were purchased: hard-shell capsules, softgels, tablets, caplets (smooth-coated tablets), liquids and powders. Two lots of each product (n=32) were purchased from the three major sales channels: mass market retail (e.g., Walmart, CVS, Target), natural and specialty retail (e.g., GNC or Whole Foods), and direct sales (products sold exclusively via the web or by multi-level marketers like Amway or Herbalife). Two DS were purchased in bulk for use as in-house control materials to monitor laboratory performance over time. Samples were repackaged and sent for laboratory analysis in defined batches.

4. Laboratory Analysis and Quality Control

Laboratories analyzed sample sets using validated sample-handling protocols and appropriate methods to obtain analytical information about ingredient levels. For the catechin monomers, high-performance liquid chromatography (HPLC) using a reversed phase column with either

ultraviolet absorbance (UV) or mass spectrometric (MS) detection was used. For caffeine, HPLC with UV detection was used. Samples were sent for retesting if there was a large discrepancy among lab results or to confirm unusually high or low values.

Quality control (QC) materials, including three certified reference materials (NIST® SRM® 3255 “Green Tea Extract”, 3254 “Green Tea Leaves” and 3256 “Green Tea Solid Oral dosage”) were analyzed with each batch of samples to evaluate laboratory precision and accuracy. In addition, product duplicates and in-house control materials were included. The consistent results seen in the catechin and caffeine values for these quality control materials gave confidence in the results for these constituents in the commercial GT DS under study.

5. Statistical Methods

Laboratory data from three laboratories for two lots of each product were combined using least squares means and standard deviations (SDs) were computed for each product using a mixed model procedure. Results for EGCG (the most prevalent catechin), total catechins (TC) and Caffeine (Caf) are reported as amount per day because the labels for many of the products recommend more than one serving per day. Percentage differences from label were calculated for DS with a numeric claim for TC, EGCG or Caf.

6. Results and Discussion

The label information about the amount of GT in the 32 products (information required by FDA) ranged from 150-2000 mg/serving and 300-6000 mg/day. At the most commonly labeled level for GT material (500 mg/serving; n=9), the analytical mean values for total catechin ranged from 1.4 to 410.6 mg/serving, and from 0.5 to 314.8 mg/serving for EGCG.

The mean values for analytically measured concentrations of EGCG, total catechins, and caffeine calculated as per day dosages showed wide ranges (2.0-630, 4.2-1070, and 0.25-130 mg/day, respectively). Results were categorized by dosage form (capsule, tablet, etc.) and matrix, which included the type of green tea ingredient (extract, leaf) and any other ingredients. Two products had caffeine added as an ingredient. The most common form and matrix were capsules with GT extract (n=21) (**Table 1**).

Table 1. Mean total catechin, EGCG and caffeine content of 32 green tea dietary supplements, categorized by dosage form and matrix

Form	Matrix	n	Green Tea Ingredient labeled amount, mean	Mean measured Total Catechins	Range of measured Total Catechins	Mean measured EGCG	Range of Measured EGCG	Mean measured Caffeine	Range of measured Caffeine
			mg/day						
capsule	GT extract	21	830	366	67.7 - 1012	222	39.7 - 630	20.1	0.25 - 65.7
capsule	GT extract, leaf	5	971	354	265 - 492	208	132 - 341	32.7	1.57 - 73
capsule	GT extract, caffeine	1	1500	1069		562		130	
liquid	GT extract	2	3750	18.2	4.18 - 32.3	7.12	1.53 - 12.7	0	
powder	GT leaf	1	1000	115		54.2		17.9	
soft gel	GT extract, caffeine	1	750	466		220		123	
tablet	GT extract, mineral, leaf	1	999	665		399		40.6	

For the 23 products that voluntarily provided label claims for total catechins, EGCG or caffeine, we compared the measured results with the label claim. For the 18 products with EGCG label claims, percent differences from label ranged from 35% below label to 186% above label, with 10 products within ± 20% of label claim. For the 10 products with labeled total catechin levels, the percent differences from label ranged from 36% below label to 45% above label and for the 9 products with a label claim for caffeine, the ranges were 84% below to 70% above label (**Table 2**).

Table 2. Mean results for DS with numeric claims for total catechins, EGCG or caffeine content

Constituent	n	Range of label claims, mg/day	Analytical results: mean % difference from label	Range of % differences from label
ECGC	18	39 -700	30.8 (13.1*)	-35 to 51 (158, 186)
Total Catechin	10	125 - 1050	13.9	-36 to +45
Caffeine	9	25 -195	-9.1	-84 to +71

*If two outliers removed

The two liquid GT DS had the lowest levels of all the constituents measured, despite having the highest levels of GT claimed. The caffeine content in these products was low, except for the two products with added caffeine. Products labeled as decaffeinated (n=6) averaged 1.7 mg caffeine/day and one product listed as a low caffeine DS contained 11.7 mg/day.

In summary, the GT DS in these (relatively) simple matrices have a variety of label formats and a wide range of labeled amounts for GT. However, the information about the weight of GT may not permit accurate predictions for the content of specific phytochemical constituents, because green tea extracts may or may not be highly concentrated and they are often microencapsulated (adds additional weight) for improved shelf life. Voluntary label information (e.g., listing amounts of EGCG or caffeine) is associated with a higher level of the actual phytochemical content, on average, compared to products without such information.

It is important to track the intake of phytochemicals, especially those that have intakes from both foods and supplements to evaluate their health effects. In a recent evaluation of flavonoid intake in NHANES 2007-08 using the USDA Flavonoid Values for Survey Foods and Beverages 2007–2008 (Bhagwat and Haytowitz, 2015), the mean U.S. daily intake of flavonoids was estimated to be 251 mg (with 81% from catechins) (Sebastion, et. al, 2015). If you compare that number to the analytical results for total catechins in the GT DS studied, 19 products would provide more flavonoids per day than the average daily estimate of 251 mg from foods and beverages.

9**. Future Research**

A second GT study (multi-ingredient GT) is in progress to evaluate the content of catechins and caffeine in complex matrices that include several botanical ingredients along with minerals, vitamins and/or other compounds. These botanical products were marketed for the purposes of weight loss, increasing energy, sports performance or increasing intake of antioxidants or bioflavonoids. Approximately half of the 36 products listed a label claim for green tea on the label. The other half listed green tea as part of a blend (these products are not required to list the amounts of ingredients within a blend—only the weight of the total blend).

The efficacy of a DS is determined not only by the amount of one or more active ingredients but also by the design and performance of the formulations into which they are incorporated. Currently, we are studying whether commercially sold single- and multi-ingredient green tea dietary supplements meet the United State Pharmacopeia general chapter specifications for disintegration and dissolution for immediate release formulations.

9. References

Bhagwat, S., Haytowitz, D.B. 2015. USDA Database for the Flavonoid Content of Selected Foods, Release 3.2. U.S. Department of Agriculture, Agricultural Research Service. Nutrient Data Laboratory Home Page: http://www.ars.usda.gov/nutrientdata/flav

Sebastion, Rhonda S, Wilkinson, Cecilia E, Goldman Joseph D, Martin Carrie L, Steinfeldt, Lois C, Murayi, Theophile, and Moshfegh, Alanna J. 2015. A New Database Facilitates Characterization of Flavonoid Intake, Sources, and Positive Associations with Diet Quality among US Adults. J Nutr 145:1239–48.