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(54) Title: COMPOSITION COMPRISING TEA SOLIDS

(57) Abstract: The present invention relates to a composition comprising tea solids, specifically a composition comprising gallo- catechin (GC) and epigallocatechin gallate (EGCG), which may be useful for weight management in a human or animal, as well as to use of the composition and a method of weight management in a human or an animal.



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TITLE

COMPOSITION COMPRISING TEA SOLIDS

FIELD OF THE INVENTION

[0001] The present invention relates to a composition comprising tea solids, specifically a composition comprising gallic catechin (GC) and epigallocatechin gallate (EGCG), which may be useful for weight management in a human or animal.

BACKGROUND

[0002] Tea, especially green tea, contains catechins that have been shown to have an effect on metabolism and therefore be useful in weight management (*Dulloo et al*, (1999) *Am J Clin Nutr* 70, p.1040). *Rudelle et al*. (2007) *Obesity* 15, p. 349, showed that a composition comprising an extract of green tea, caffeine and calcium increased energy expenditure in healthy adults. The supposed metabolic effect of tea has especially been ascribed to one of the catechins present in tea, epigallocatechin gallate (EGCG). However, the present inventors have analysed the tea extract used by *Rudelle et al.*, and have found that this is characterised by a epigallocatechin gallate (EGCG) to total catechins ratio and which is lower than in other green tea extracts showed to induce a significant increase in energy expenditure (*Rumpler et al* (2001) *J.Nutr* 131 p.2848; *Berube-Parent et al* (2005) *Br.J.Nutr* 94, p.432), *Dulloo et al* (1999) *Am J Clin Nutr* 70, p.1040). It also differs by a higher content of gallic catechin (GC), and a higher ratio of gallic catechin (GC) to epigallocatechin gallate (EGCG). The inventors have confirmed the effect on energy expenditure found by *Rudelle et al.*, and have furthermore surprisingly found that a composition comprising the tea extract of *Rudelle et al.* but without calcium is even more effective in increasing energy expenditure and fat oxidation. Of interest is that this tea composition with no calcium induced a significant increase in energy expenditure although it contained less EGCG and total catechins and was administered together with a lower dose of caffeine compared to others (*Rumpler et al* (2001) *J.Nutr* 131 p.2848; *Berube-Parent et al* (2005) *Br.J.Nutr* 94, p.432), *Dulloo et al* (1999) *Am J Clin Nutr* 70, p.1040).

SUMMARY OF THE INVENTION

[0003] Accordingly, the present invention relates to a composition comprising tea solids, wherein the amount of gallic catechin (GC) is at least 5% of the amount of

epigallocatechin gallate (EGCG), and the amount of calcium is less than 100 mg per g of total tea solids. In further embodiments the invention relates to use of a composition of the invention as well as a method of weight management in a human or an animal.

BRIEF DESCRIPTION OF THE FIGURES

[0004] Figure 1: Comparison between treatments for the difference between resting and postprandial energy expenditure (kcal/h). n= 44. Mean of valid values $\pm$ SE. * P< 0.001 vs placebo.

[0005] Figure 2: Comparison between treatments for the difference between resting and postprandial fat, carbohydrate and protein oxidation (mg/min). n=44. Median all values $\pm$ SD. * p<0.001 vs placebo; ** p<0.05 vs Dynamite.

DETAILED DESCRIPTION OF THE INVENTION

[0006] The present invention provides a composition comprising tea solids. By tea solids are understood any solid derived from a tea plant (*Camellia sinensis*, such as e.g. *C. sinensis sinensis* and *C. sinensis assamica*). The tea solids may be derived from any part of the tea plant, such as e.g. leaves, twigs, and/or stems. In a preferred embodiment tea solids are derived from the leaves of a tea plant. Tea solids according to the invention are preferably green tea solids. By green tea solids is meant tea solids derived from green tea leaves, i.e. tea leaves which have been subjected to no or only a mild and short oxidation process, also referred to as fermentation, as opposed to black tea which is oxidised more intensively. Green tea leaves are usually heat treated, e.g. with steam or by dry heating in pans shortly (e.g. within 1 to 2 days) after harvesting to stop enzymatic oxidation processes. Tea solids may be derived from tea plant by any suitable method. Suitable methods for extraction of tea solids are well known in the art. After extraction, tea solids may be treated by any suitable method to obtain tea solids with the desired composition, tea solids may e.g. be fractionated by chromatographic, membrane and other fractionation methods. In a preferred embodiment, tea solids are water soluble. In a preferred embodiment, the composition of the invention comprises at least 0.5 mg of tea solids per gram, such as between 0.5 mg and 100 mg of tea solids, or between 1 mg and 50 mg, per gram.

[0007] The composition of the invention comprises gallocatechin (GC) and epigallocatechin gallate (EGCG). The amount of gallocatechin (GC) is at least 5% (weight/weight) of the amount of epigallocatechin gallate (EGCG), preferably at least 10% of

the amount of epigallocatechin gallate (EGCG). In a preferred embodiment the amount of gallocatechin (GC) is at least 8 mg per gram of total tea solids, more preferably at least 15 mg, such as between 15 mg and 200 mg per gram of total tea solids.

[0008] In a preferred embodiment, the composition comprises an amount of between 50 and 500 mg of epigallocatechin gallate (EGCG) per gram of total tea solid, such as between 100 mg and 300 mg per gram of total tea solids.

[0009] A composition according to the invention may comprise additional catechins, e.g. epigallocatechin (EGC) (e.g. in an amount of between 40 mg and 160 mg per gram of total tea solids); catechin (C) (e.g. in an amount of between 3 mg and 25 mg per gram of total tea solids); epicatechin (EC) (e.g. in an amount of between 8 mg and 70 mg per gram of total tea solids); gallocatechin gallate (GCG) (e.g. in an amount of between 3 mg and 30 mg per gram of total tea solids); epicatechin gallate (ECG) (e.g. in an amount of between 10 mg and 100 mg per gram of total tea solids); and/or catechin gallate (CG) (e.g. in an amount of between 0.5 mg and 10 mg per gram of total tea solids). The total amount of catechins in the composition of the invention is preferably between 10% and 100% (weight/weight) of the total tea solids, such as between 20% and 50% of the total tea solids.

[0010] The amount of calcium in the composition of the invention is less than 100 mg per g of total tea solids, preferably less than 50 mg, more preferably less than 20 mg per g of total tea solids. In another embodiment the amount of calcium in the composition is preferably less than 500 mg per g, such as less than 100 mg per g, or less than 10 mg per g. In a preferred embodiment of the invention the composition is substantially free of calcium.

[0011] The composition of the invention may further comprise caffeine, preferably in an amount of between 50 mg and 300 mg of caffeine per g of tea solids, such as between 100 mg and 200 mg of caffeine per g of tea solids. Caffeine may be from any source, it may e.g. be from tea and thus forming part of the tea solids of the composition, it may be derived from coffee, other caffeine producing plants such as e.g. guarana and/or yerba mate, and/or it may be synthetic.

[0012] The composition of the invention may be in any form suitable for ingestion by a human and/or an animal, e.g. in liquid, powder, paste, semi-solid or solid form. An animal according to the invention may be any animal, e.g. a dog or cat. In a preferred embodiment of the invention, the composition is a beverage, a food product, a medical nutrition product, an infant nutrition product, a food supplement, or a pet food product. A food product according to the invention may be any food product, e.g. a nutritional bar and/or a sports or

performance nutrition product. A food supplement may be in any suitable form, e.g. as a pill, capsule, powder or liquid. A beverage, a food product, a medical nutrition product, an infant nutrition product, a food supplement, or a pet food product according to the invention preferably comprises between 250 mg and 1250 mg of total tea solids per serving, such as e.g. between 500 mg and 1000 mg of total tea solids per serving. If caffeine is present, it is preferably present in an amount of between 30 mg and 300 mg, such as between 50 mg and 200 mg, per serving. In a preferred embodiment a beverage, a food product, a medical nutrition product, an infant nutrition product, a food supplement, or a pet food product according to the invention preferably comprises between 5 mg and 150 mg of gallic acid (GA), preferably between 10 mg and 50 mg, per serving, and/or between 30 and 500 mg, preferably between 50 mg and 300 mg, of epigallocatechin gallate (EGCG) per serving.

[0013] A beverage according to the invention may be any beverage, including a beverage concentrate and a beverage powder intended for the preparation of a beverage, e.g. by addition of water. In one embodiment a beverage comprises between 1 mg and 5 mg of total tea solids per mL, such as between 2 mg and 4 mg of total tea solids per mL. If the beverage is a beverage concentrate or beverage powder for preparing a beverage, it preferably comprises tea solids in an amount to provide between 1 mg and 5 mg of total tea solids, such as between 2 mg and 4 mg of total tea solids, per mL when a beverage is prepared in the recommended way. A beverage according to the invention preferably comprising between 0.02 mg and 0.2 mg, such as between 0.05 mg and 0.1 mg, of gallic acid (GA) per mL. If the beverage is a beverage concentrate or beverage powder for preparing a beverage, it preferably comprises gallic acid (GA) in an amount to provide between 0.02 mg and 0.2 mg, such as between 0.05 mg and 0.1 mg, of gallic acid (GA) per mL when a beverage is prepared in the recommended way. A beverage according to the invention is preferably a weight management beverage, i.e. a beverage intended for ingestion by a human or an animal for weight management in said human or animal. A beverage according to the invention may include any other compounds or ingredients suitable for inclusion in a beverage for the consumption of a human or an animal, such as e.g. flavours, sweeteners, colours, stabilisers, preservatives, texturising agents, acids, buffers, and the like.

[0014] The invention further relates to use of a composition according to the invention for weight management in a human or animal. By weight management in a human or animal is meant any use intended to reduce or avoid weight gain, or to achieve weight loss. Use of a composition of the invention for weight management may e.g. be performed as

detailed below.

[0015] In one embodiment of the invention, a method for weight management in a human or animal, comprises the step of causing the ingestion by said human or animal of a composition of the invention. Preferably, the composition of the invention to be ingested is effective to increase the energy expenditure and/or the fat oxidation rate of said human or animal. Ingestion by a human may e.g. be caused by providing directions to the human subject in question to ingest the composition of the invention, e.g. by instructions on the package of the composition, or instructions otherwise provided in relation to the composition. Ingestion by a human or animal may also be caused by serving the composition to the human or animal. The method for weight management of the invention preferably comprises the step of causing a human or an animal to ingest an effective amount of a composition of the invention, e.g. an amount effective to increase the energy expenditure and/or the fat oxidation rate of the human or animal. The method of the invention preferably comprises the step of causing the ingestion by said human or animal of a composition of the invention at regular intervals over a period of time, such as e.g. between 1 and 3 times a day for at least 2 days, such as at least 5 days.

[0016] In a preferred embodiment the method of weight management comprises the step of causing the ingestion by a human or animal of between 50 and 600 mg of epigallocatechin gallate (EGCG), more preferably between 50 and 200 mg of epigallocatechin gallate (EGCG); and/or the ingestion of between 10 and 120 mg of gallic acid (GA), more preferred between 10 and 30 mg of gallic acid (GA); during a period of 24 hours. Preferably the method additionally comprises the step of causing the ingestion by said human or animal of between 50 mg and 600 mg of caffeine, more preferred between 50 mg and 200 mg of caffeine, during said period of 24 hours. Even more preferably, the step of causing said ingestion by said human or animal during a period of 24 hours is repeated over 2 or more consecutive days, such as over 5 or more consecutive days.

[0017] In one embodiment of the invention, weight management is non-medical weight management, i.e. not weight management intended for the medical treatment of overweight or obesity. In another embodiment, the invention relates to use of a composition of the invention in the manufacture of a medicament for weight management in a human or animal. A medicament may be in any suitable form, e.g. a pill, tablet, powder or liquid, and may include any suitable compounds suitable for the production of a medicament.

EXAMPLE 1

Tea extract

[0018] The tea extract used is a powdered cold and hot-water soluble extract of green tea leaves obtained from the Nestlé Choladi factory (Choladi, India). The tea extract was dissolved in water to produce a beverage with the following composition:

	mg/250 ml	SD	%
GC	20	5	
EGC	63	15	
C	6	1	
EC	18	1	
EGCG	116	5	
GCG	8	1	
ECG	28	1	
CG	2	1	
Total catechins	268	23	
Total green tea extract	770		
Caffeine	104	5	5
Catechins	268		37
Non catechin polyphenols (gallic acid and flavanol- glycosides)	1		5-8
Theaflavins			0
Thearubigins			0
Amino Acids			6
Minerals			10
Carbohydrates (by calculation)			30

Clinical study

[0019] The study was a placebo-controlled, randomized, double-blind, crossover clinical trial with three treatment groups. Treatments were in a 250 ml size format and all contained < 10 kcal:

1. 250 ml of the green tea beverage described above with 207 mg calcium added, 6.5 kcal/245g serving
2. 250 ml of the green tea beverage described above, 2.7 kcal/245g serving
3. Placebo: no caffeine, green tea or calcium, 6.7 kcal/245g serving

[0020] Participants were young, healthy males and females who received the treatments in a random order with a washout period of at least 9 days for men and 21 days for women. Women were tested in the follicular phase of their cycle.

[0021] The day before each test, the subjects consumed 3 controlled meals (breakfast, lunch and dinner), and spent the night at the Investigation site where tests were performed the next morning. The quantities of food items consumed by the participants on the first occasion were served on the following two occasions preceding the test day.

[0022] On the morning of the test, the participants were woken at ~6:00AM and their urine was collected in the same container as that used to collect the overnight urine. Immediately after, participants were comfortably installed, in a semi-recumbent position, in a bed. An armband was installed on the right arm to measure blood pressure, and a canopy was installed over the participants head. Metabolic rate measurement was started immediately for 75 min in an open-circuit, ventilated-hood connected to an open-circuit indirect calorimeter (Vmax Encore V29n gas analyzer, Viasys-Healthcare (Hoechberg, Germany)), SEBAC MSR (Gennevilliers, France), and the last 30 minutes of the measurement was used to calculate resting energy expenditure and substrate utilization. Immediately after, one of the three test beverages was consumed within a period of 5 minutes. During this period, the canopy was removed to allow participant to sit in the bed and drink the beverage using a straw. Following beverage ingestion, the canopy was installed again over the participants head and metabolic rate measurements were continued for another 4 hours and used to calculate post-ingestion energy expenditure and substrate oxidation. Every 30 minutes of the test heart rate and blood pressure were recorded using the Colin Press Mate, BP-8800/8800C (Colin Corporation, Komaki, Japan) and the Dinamap Pro 100 VR (GE Medical Systems, Milwaukee, USA). At the end of the test, urine was collected in a different container and a meal was served to participants.

Calculations and analysis

[0023] Energy expenditure was calculated using Weir's formula (*Weir* (1949), *J Physiol* 109, p.1). Carbohydrate and fat utilization were calculated from the respiratory exchange data using standard equations (*Livesey and Elia*, (1988), *Am J Clin Nutr* 47, p.608)

[0024] Protein oxidation was calculated from urine nitrogen. Urine nitrogen was determined using the standard method of Kjeldahl for organic nitrogen analysis. Urines were collected in 2 L bottles prior to volume measurements. Urine was collected during the night (from 22h) and in the morning preceding metabolic rate measurement (Container 1, fasting-resting period) and at the end of the 240 min measurement period (Container 2, post-prandial period). Aliquots (150 mL) of urines were transferred into vials containing 1 mL of concentrated sulfuric acid. Aliquots were stored at -80°C until analyses.

[0025] Resting baseline heart rate and blood pressure values were calculated as the mean of measurements at 30 and 60 min. Post-ingestion heart rate and blood pressure were measured immediately after ingestion of the test beverages and every 30 min during the 240 min post-ingestion period.

Results

Energy expenditure

[0026] The primary outcome of this study was the difference between resting and postprandial energy expenditure (kcal/h), which represents the capacity of the test beverages to increase energy expenditure above resting values.

[0027] Figure 1 illustrates the mean increase in energy expenditure above resting values following ingestion of the three beverages. Beverage without calcium (Dynamite noCa²⁺) increased energy expenditure significantly more than the placebo beverage (+ 2.38 kcal/h, $p = 0.0008$). The beverage with calcium (Dynamite) also increased energy expenditure compared to the placebo beverage, but not to a significant extent (+1.17 kcal/h, $p=0.2023$). The placebo beverage increased energy expenditure by 1.9 kcal/h.

Substrate oxidation

[0028] Figure 2 shows the results regarding substrate oxidation. Beverage without calcium (Dynamite noCa²⁺) increased fat oxidation significantly more than placebo (8.10 mg/min, $p=0.0082$). This was reflected in the significant decrease in the respiratory quotient (-0.018, $p=0.0426$). In contrast, beverage with calcium (Dynamite) induced a small non-significant decrease in fat oxidation compared to placebo.

Blood pressure and Heart rate

[0029] No difference could be found between treatments for development over time of heart rate and blood pressure.

CLAIMS

1. A composition comprising tea solids, wherein the amount of gallocatechin (GC) is at least 5% of the amount of epigallocatechin gallate (EGCG), and the amount of calcium is less than 100 mg per g of total tea solids.
2. The composition of claim 1 wherein the tea solids are green tea solids.
3. The composition of claim 1 or 2 further comprising between 50 mg and 300 mg of caffeine per g of tea solids.
4. The composition of any of the previous claims wherein the amount of gallocatechin gallate is at least 10% of the amount of epigallocatechin gallate.
5. The composition of any of the previous claims wherein the amount of calcium is less than 20 mg per g of total tea solids.
6. The composition of any of the previous claims, wherein the composition is a beverage, a food product, a medical nutrition product, an infant nutrition product, a food supplement, or a pet food product.
7. The composition of claim 6 comprising between 250 mg and 1250 mg of total tea solids per serving.
8. The composition of claim 6 or 7, wherein the composition is a beverage comprising between 1 mg and 5 mg of total tea solids per mL.
9. A beverage of any of the claims 6-8 comprising between 0.02 mg and 0.2 mg of gallocatechin (GC) per mL.
10. The composition of any of claims 6-9 wherein the composition is a weight management beverage.

11. Use of a composition according to any of the previous claims for weight management in a human or animal.

12. Use of a composition of any of claims 1-5 in the manufacture of a medicament for weight management in a human or animal.

13. A method for weight management in a human or animal, comprising the step of causing the ingestion by said human or animal of a composition according to any of claims 1-10.

14. The method of claim 13, comprising the step of causing the ingestion by said human or animal of between 50 and 600 mg of epigallocatechin gallate (EGCG) and/or the ingestion of between 10 and 120 mg of gallic acid (GA), during a period of 24 hours.

15. The method of claim 14 further comprising the step of causing the ingestion by said human or animal of between 50 mg and 600 mg of caffeine during said period of 24 hours.

16. The method of claim 14 or 15, wherein the step of causing said ingestion by said human or animal during a period of 24 hours, is repeated over 2 or more consecutive days.

17. The method of any of claims 13-16 wherein the composition is effective to increase the energy expenditure and/or the fat oxidation rate of said human or animal.

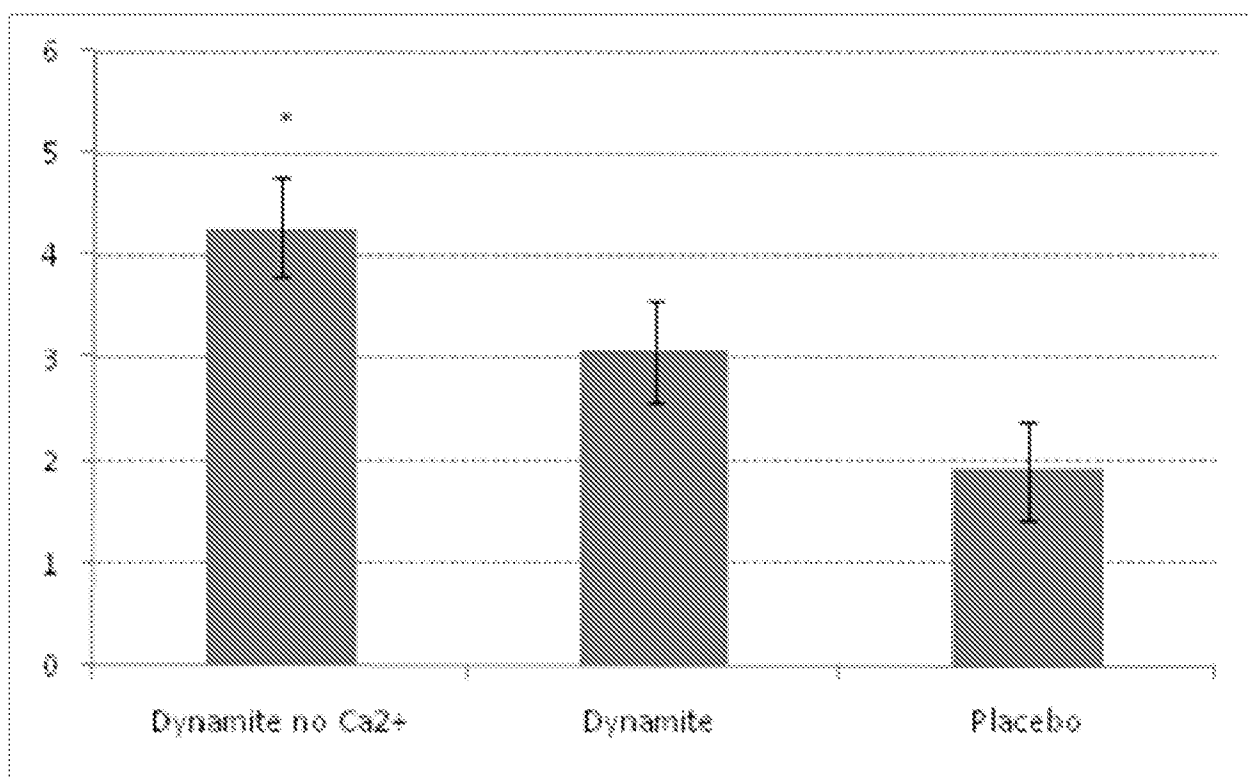
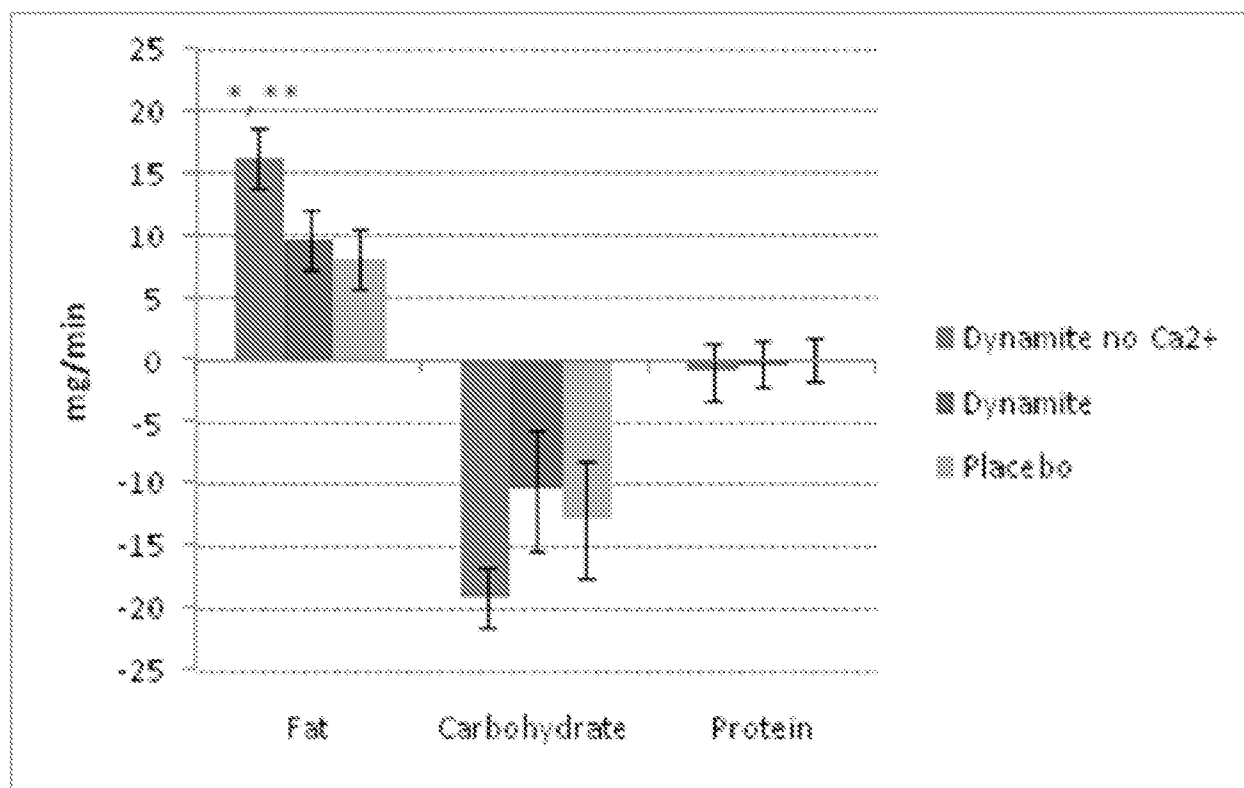
Figure 1

Figure 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/048138

A. CLASSIFICATION OF SUBJECT MATTER

INV. A23F3/00 A23F3/16 A23L1/29 A23L1/30 A61K36/82
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A23F A23L A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, FSTA, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	RUDELLE SERVANE ET AL: "Effect of a thermogenic beverage on 24-hour energy metabolism in humans", OBESITY, NATURE PUBLISHING GROUP, US, vol. 15, no. 2, 1 February 2007 (2007-02-01), pages 349-355, XP002467751, ISSN: 1930-7381 cited in the application page 350, column 2 ----- -/--	1-10



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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Name and mailing address of the ISA/

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Pfannenstein, Heide

INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Week 200308 Thomson Scientific, London, GB; AN 2003-084863 XP002637883, & JP 2002 326932 A (KAO CORP) 15 November 2002 (2002-11-15) abstract -----	1-17
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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