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(54) Title: NOVEL USE OF (-)-EPIGALLOCATECHIN GALLATE

(57) Abstract: The present invention refers to the use of (-)-epigallocatechin gallate, preferably in combination with a sympathomimeticum, for increasing/stimulating the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, especially during postprandial conditions; supporting the metabolism of fat in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans; for reducing the weight of mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans; for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans; for increasing the endurance in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans; for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans; for reducing the respiratory quotient in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans; and for improving the flow mediated dilation, thereby contributing to the beneficial effects on coronary health, in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans. The preferred sympathomimeticum is caffeine. The invention further refers to the corresponding methods. Preferably the (-)-epigallocatechin gallate has a purity of at least 80% or higher. More preferably it is obtained by any of the processes described in US 6,383,392, EP 1 103 550, US 10/246 112 and EP 1 077 211.

Novel use of (–)-epigallocatechin gallate

The present invention refers to the use of (–)-epigallocatechin gallate (EGCG), preferably in combination with a sympathomimeticum,

- 5 – for increasing/stimulating the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, especially during post prandial conditions;
- for supporting the metabolization of fat in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans;
- 10 – for reducing the weight of mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans;
- for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans;
- for increasing the endurance in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans;
- 15 – for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans;
- for reducing the respiratory quotient in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans; and
- 20 – for improving the flow mediated dilation, thereby contributing to the beneficial effects on coronary health, in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans.

The preferred sympathomimeticum is caffeine. The invention further refers to the corresponding methods.

Uses

A first object of the present invention is the use of EGCG for increasing the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans. The fat oxidation encompasses the pre-prandial, prandial and post-prandial fat oxidation, i.e. the fat (= lipid) oxidation before, during and after the meals taken by the mammals selected from the group consisting of humans, cats, dogs and horses, preferably by the humans. EGCG has especially an influence on the prandial and post-prandial fat oxidation. The EGCG may be administered in the form of (fortified) food or (fortified) feed, dietary supplements, beverages, tablets, granules, capsules, pastes, food additives, feed additives, or effervescent formulations. If it is administered in the form of a beverage, it shows its positive influence on the fat oxidation faster than if it is administered in the form of a capsule. In a preferred embodiment of the present invention EGCG is therefore administered in such a way that it is present or moreover that its concentration is at a high level during the intake of food/feed/beverages, especially during the fat intake, of the mammal. That means that EGCG is preferably administered before or simultaneously with the food/feed/beverages. In a preferred embodiment of the invention the EGCG is part of the food/feed. Examples are cereal bars containing EGCG. In a preferred embodiment of the present invention EGCG is used in combination with a sympathomimeticum. Especially preferred is also the use of compositions such as dietary supplements consisting essentially of EGCG and caffeine. Advantageously the energy expenditure is not changed by the increased fat oxidation induced by the use of EGCG.

A second object of the present invention is the use of EGCG for supporting the metabolism of fat in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans. In a preferred embodiment of this object of the present invention EGCG is therefore administered in such a way that it is present or moreover that its concentration is at a high level during the intake of food/feed/beverages, especially during the fat intake, of the mammal selected from the group consisting of humans, cats, dogs and horses, preferably of the humans. That means that EGCG is preferably administered before or simultaneously with the food/feed/beverages. In a preferred embodiment of the invention the EGCG is part of the food/feed. Examples are cereal bars containing EGCG.

A third object of the present invention is the use of EGCG for reducing the weight of mammals selected from the group consisting of humans, cats, dogs and horses, preferably the weight of humans. In a preferred embodiment of this object EGCG is used in combination with a sympathomimeticum.

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A fourth object of the present invention is the use of EGCG for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans. In a preferred embodiment of this object EGCG is used in combination with a sympathomimeticum. Especially the visceral and/or the subcutaneous fat is reduced by the use of EGCG, preferably in combination with a sympathomimeticum. The visceral fat layer is considered an important element in the development of the metabolic syndrome.

A fifth object of the present invention is the use of EGCG, preferably in combination with a sympathomimeticum, for increasing the endurance in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans. Therefore, the present invention is also directed to sport beverages containing EGCG, preferably highly purified EGCG as defined below, more preferably in combination with caffeine.

A sixth object of the present invention is the use of EGCG for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans. In a preferred embodiment of this object EGCG is used in combination with a sympathomimeticum.

A seventh object of the present invention is the use of EGCG for reducing the respiratory quotient in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans. In a preferred embodiment of this object EGCG is used in combination with a sympathomimeticum.

Respiratory quotient (RQ)

Animal cells obtain energy in the form of ATP by oxidizing food molecules through the process of respiration. Carbohydrates and fatty acids are the most important fuels for generating ATP in animal cells.

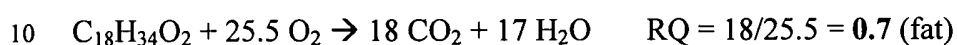
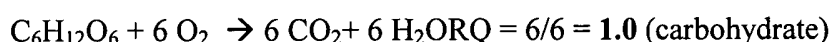
The respiratory quotient (RQ) measures the ratio of the volume of carbon dioxide ($V(\text{CO}_2)$) produced by an organism to the volume of oxygen consumed ($V(\text{O}_2)$).

$$\text{RQ} = V(\text{CO}_2) / V(\text{O}_2)$$

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The volumes of O_2 and CO_2 are measured by **indirect calorimetry**

The RQ depends on which fuel source is being metabolized:



An eighth object of the present invention is the use of EGCG for improving the flow mediated dilation, thereby contributing to the beneficial effects on coronary health, in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans.

15 EGCG acutely increases the flow mediated dilation thereby improving the endothelial function. EGCG elicits this effect when present in plasma. Endothelial function is regarded as an important element in the development of the metabolic syndrome. Thus, EGCG prevents the development of the metabolic syndrome.

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In preferred embodiments of the present invention the used EGCG has a purity of at least 80%, preferably of at least 85%, more preferably of at least 90%, even more preferably of at least 92%, most preferably of at least 94%. Especially preferred is also an aqueous green tea extract containing EGCG in an amount of at least 80% (preferred of at least 85%, more preferred of at least 90%, even more preferred of at least 92%, most preferred of at least 94%), based on the total amount of the extract, as e.g. and preferably obtained by any of the processes described in US 6,383,392, EP 1 103 550, US 10/246 112 and EP 1 077 211. Preferably the total amount of other polyphenols and catechins such as gallic acid, gallic acid gallate, catechin gallate, epicatechin gallate, epigallocatechin gallate, gallic acid and epigallocatechin is low, preferably it is ≤ 5 weight-%, based on the total weight of the green tea extract. More preferably the amount of gallic acid gallate is ≤ 2.5 weight-%, and/or the amount of epicatechin gallate is ≤ 5 weight-% (preferably ≤ 3 weight-%), and/or the amount of caffeine is ≤ 2.5 weight-%, preferably ≤ 0.1 weight-%, and/or the amount of gallic acid is ≤ 0.1 weight-%, based on the total weight of the green tea extract.

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A sympathomimeticum is a substance that stimulates the sympathetic nervous system. A preferred example of such a substance is caffeine. Therefore the present invention refers to the use of a combination of EGCG and caffeine for the uses as given above. If caffeine is
5 used in combination with EGCG the daily dosage of caffeine varies preferably from 2.5 mg per kg body weight to 7.5 mg per kg body weight.

Other examples of sympathomimetica that may be used in combination with EGCG are theophylline, theobromine or extracts of xanthine containing plants such as cacao plants,
10 coffee plants, barley and ginger.

The sympathetic nervous system is also stimulated by physical activity such as sport, so that sport can also be seen as sympathomimeticum. Therefore, the present invention relates also to the use of EGCG as given above, preferably of highly purified EGCG as defined
15 above, in combination with physical activity.

Preferred subjects for the uses/methods of the present invention are humans.

In preferred embodiments of the uses as given above the daily dosage of EGCG varies
20 from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

Thus, for humans with a weight of 70 kg, the daily dosage of EGCG varies from 10 to
25 1500 mg, preferably from 150 to 600 mg, more preferably from 300 to 600 mg, most preferably it is 300 mg.

Methods

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A ninth object of the present invention is a method for increasing the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of EGCG, preferably in combination with an effective dose of a sympathomimeticum, to a mammal

selected from the group consisting of humans, cats, dogs and horses, preferably to a human, which is in need thereof, characterized in that the effective dose of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg
5 body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

A tenth object of the present invention is a method for supporting the metabolism of fat in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of
10 EGCG, preferably in combination with an effective dose of a sympathomimeticum, to a mammal selected from the group consisting of humans, cats, dogs and horses, preferably to a human, which is in need thereof, characterized in that the effective dose of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg
15 body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

An eleventh object of the present invention is a method for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of EGCG,
20 preferably in combination with a sympathomimeticum, to a mammal selected from the group consisting of humans, cats, dogs and horses, preferably to a human, which is in need thereof, characterized in that the effective dose of EGCG varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg
25 per kg body weight per day.

A twelfth object of the present invention is a method for reducing the weight of mammals selected from the group consisting of humans, cats, dogs and horses, preferably for reducing the weight of humans, said method comprising the step of administering an effective
30 dose of EGCG, preferably in combination with a sympathomimeticum, to a mammal selected from the group consisting of humans, cats, dogs and horses, preferably to a human, which is in need thereof, characterized in that the effective dose of EGCG varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per

day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

A thirteenth object of the present invention is a method for increasing the endurance in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of EGCG, preferably in combination with a sympathomimeticum, to a mammal selected from the group consisting of humans, cats, dogs and horses, preferably to a human, which is in need thereof, characterized in that the effective dose of EGCG varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

A fourteenth object of the present invention is a method for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of EGCG, preferably in combination with a sympathomimeticum, to a mammal selected from the group consisting of humans, cats, dogs and horses, preferably to a human, which is in need thereof, characterized in that the effective dose of EGCG varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

In preferred embodiments of the methods as given above, the methods further comprise the step of the mammals selected from the group consisting of humans, cats, dogs and horses performing physical activity, preferably the methods further comprise the step of the humans performing physical activity.

A fifteenth object of the present invention is a method for reducing the respiratory quotient in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of (–)-epigallocatechin gallate, preferably in combination with a sympathomimeticum, to a mammal selected from the group consisting of humans, cats, dogs and horses, preferably to a human, which is in need thereof, characterized in that the effective dose of (–)-epigallo-

catechin gallate varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

- 5 A sixteenth object of the present invention is a method for improving the flow mediated dilation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, thereby contributing to a beneficial effect on the coronary health, said method comprising the step of administering an effective dose of (–)-epigallocatechin gallate to a mammal selected from the group consisting of humans, cats, dogs and horses,
10 preferably to a human, which is in need thereof, characterized in that the effective dose of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.
- 15 In further preferred embodiments of the methods as given above the mammals are humans with a body mass index above 25. The body mass index is the number obtained by dividing the body weight in kilogramm of a human by the square of its height in meters.

- In especially preferred embodiments of the methods as given above the EGCG has a purity
20 of at least 80%, preferably of at least 85%, more preferably of at least 90%, even more preferably of at least 92%, most preferably of at least 94%. Especially preferred is an EGCG obtained by any of the processes described in US 6,383,392, EP 1 103 550, US 10/246 112 and EP 1 077 211.

- 25 As already stated above the EGCG may be administered in the form of (fortified) food or (fortified) feed, dietary supplements, beverages, food additives, or feed additives.

- Non-limiting examples of food, especially for humans, are dairy products such as yoghurts, cereal bars and bakery items such as cakes and cookies; but EGCG may also be added to
30 any other food/feed a mammal selected from the group consisting of humans, cats, dogs and horses regularly eats. Food may also be in liquid form such as soups and dairy products (muesli drinks).

Non-limiting examples of beverages for humans are non-alcoholic drinks such as soft drinks, sport drinks, fruit juices, lemonades, near-water drinks (i.e. low calorie drinks based on water), teas and milk based drinks.

- 5 Preferred forms of dietary supplements are tablets, pills, granules, dragées, capsules, and effervescent formulations.

If EGCG is administered in the form of a beverage, it shows its positive influence on the fat oxidation and the endurance faster than if it is administered in the form of a capsule. In
10 a preferred embodiment of the present invention EGCG is therefore administered in such a way that it is present or moreover that its concentration is at a high level during the intake of food/feed/beverages, especially during the fat intake, of the mammal selected from the group consisting of humans, cats, dogs and horses, preferably of the human, and during the activity for which endurance is needed, respectively. That means that EGCG is preferably
15 administered before or simultaneously with the food/feed/beverages. In an especially preferred embodiment of the present invention the (composition/dietary supplement containing) EGCG is incorporated by the mammal selected from the group consisting of humans, cats, dogs and horses, preferably of the human, at least half an hour before the intake of food, feed or beverages, preferably at a point in time between 0.5 and 1.5 hours before the
20 intake of food, feed or beverages. If EGCG is administered in form of fortified food, feed or beverages it is simultaneously incorporated by the mammal selected from the group consisting of humans, cats, dogs and horses, preferably of the human, with such fortified food, feed or beverage.

- 25 In a preferred embodiment of the present invention EGCG is used in combination with a sympathomimeticum.

The present invention is also directed to the use of (–)-epigallocatechin gallate, preferably in combination with a sympathomimeticum, for the manufacture of a composition
30 – for increasing the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans;♦
– for supporting the metabolism of fat in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans;♦

- for reducing the weight of mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans;
 - for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans;
 - 5 – for increasing the endurance in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans;●
 - for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans;
 - for reducing the respiratory quotient in mammals selected from the group consisting
10 of humans, cats, dogs and horses, preferably in humans;
 - for improving the flow mediated dilation, thereby for contributing to the beneficial effects on coronary heart, in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans.
- 15 ♦ In preferred embodiments of the present invention the composition is administered in such a way that (–)-epigallocatechin gallate is present in the body during the intake of food/feed/beverages of the mammal, preferably that it is present in a high concentration in the body during the intake of food/feed/beverages of the mammal selected from the group consisting of humans, cats, dogs and horses, preferably of the human.
- 20 ● In preferred embodiments of the present invention the composition is administered in such a way that (–)-epigallocatechin gallate is present, preferably in high concentration, in the body when the mammal selected from the group consisting of humans, cats, dogs and horses, preferably when the human, is performing the activity for which endurance is
25 needed.

The preferences mentioned above for (–)-epigallocatechin gallate, the sympathomimeticum, the mammals, the form in which the composition is administered, and the daily dosage of (–)-epigallocatechin gallate also apply here.

30 Also objects of the present invention are the methods according to claims 26 to 38.

Further objects of the present invention are:

* Use of a dietary supplement containing (–)-epigallocatechin gallate for increasing the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal before the regular
5 intake of food, feed or beverages containing said fat whose oxidation is increased.

* Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the weight of a mammal selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal before the intake of food,
10 feed or beverages.

* Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal before the intake of food,
15 feed or beverages.

* Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal before the
20 regular intake of food, feed or beverages containing said carbohydrate whose oxidation is reduced.

In preferred embodiments of these uses (*) the dietary supplement is incorporated by said mammal at least half an hour before the intake of food, feed or beverages, even more preferred at a point in time between half an hour and one and a half hour before the intake of
25 food, feed or beverages.

In preferred embodiments of these uses the EGCG has a purity of at least 80%, preferably of at least 85%, more preferably of at least 90%, even more preferably of at least 92%,
30 most preferably of at least 94%. Especially preferred is also an aqueous green tea extract containing EGCG in an amount of at least 80% (preferred of at least 85%, more preferred of at least 90%, even more preferred of at least 92%, most preferred of at least 94%), based on the total amount of the extract, as e.g. and preferably obtained by any of the processes described in US 6,383,392, EP 1 103 550, US 10/246 112 and EP 1 077 211. Preferably

the total amount of other polyphenols and catechins such as gallocatechin gallate, catechin gallate, epicatechin gallate, epigallocatechin, gallocatechin and epicatechin is low, preferably it is ≤ 5 weight-%, based on the total weight of the green tea extract. More preferably the amount of gallocatechin gallate is ≤ 2.5 weight-%, and/or the amount of epicatechin gallate is ≤ 5 weight-% (preferably ≤ 3 weight-%), and/or the amount of caffeine is ≤ 2.5 weight-%, preferably ≤ 0.1 weight-%, and/or the amount of gallic acid is ≤ 0.1 weight-%, based on the total weight of the green tea extract.

The dietary supplement preferably additionally contains a sympathomimeticum such as caffeine. Therefore the present invention refers to the use of a combination of EGCG and caffeine for the uses as given above. If caffeine is used in combination with EGCG the daily dosage of caffeine varies preferably from 2.5 mg per kg body weight to 7.5 mg per kg body weight.

The sympathetic nervous system is also stimulated by physical activity such as sport, so that sport can also be seen as sympathomimeticum. Therefore, the present invention relates also to the use of EGCG as given above, preferably of highly purified EGCG as defined above, in combination with physical activity.

Preferred subjects for the uses/methods of the present invention are humans.

In preferred embodiments of the uses as given above the daily dosage of EGCG varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

Thus, for humans with a weight of 70 kg, the daily dosage of EGCG varies from 10 to 1500 mg, preferably from 150 to 600 mg, more preferably from 300 to 600 mg, most preferably it is 300 mg.

Alternatively the dietary supplement containing (–)-epigallocatechin gallate may be incorporated by the mammal simultaneously with the food, feed or beverage, respectively. Thus, further objects of the present invention are:

◇ Use of a dietary supplement containing (–)-epigallocatechin gallate for increasing the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal simultaneously with the regular intake of food, feed or beverages containing said fat whose oxidation is increased.

◇ Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the weight of a mammal selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal simultaneously with the intake of food, feed or beverages.

◇ Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal simultaneously with the intake of food, feed or beverages.

◇ Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal simultaneously with the regular intake of food, feed or beverages containing said carbohydrate whose oxidation is reduced.

Here the same preferences as cited above apply.

In further embodiments of the present invention the food, feed or beverage itself may be fortified with (–)-epigallocatechin gallate. The advantage thereof is that the (–)-epigallocatechin gallate is incorporated by said mammal simultaneously with the intake of food, feed and beverages, respectively. Thus, further objects of the present invention are:

◇ Use of a food, feed or beverage fortified with (–)-epigallocatechin gallate for increasing the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and horses.

◇ Use of a food, feed or beverage fortified with (–)-epigallocatechin gallate for reducing the weight of a mammal selected from the group consisting of humans, cats, dogs and horses.

- 5 ◇ Use of a food, feed or beverage fortified with (–)-epigallocatechin gallate for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses.

- 10 ◇ Use of a food, feed or beverage fortified with (–)-epigallocatechin gallate for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats, dogs and horses.

In preferred embodiments of the uses as given above the food, feed or beverage is fortified with EGCG in such an amount so that the daily dosage of EGCG varies from 0.14 to 25
15 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

Thus, for humans with a weight of 70 kg, the food, feed or beverage is fortified with
20 EGCG in such an amount so that the daily dosage of EGCG varies from 10 to 1500 mg, preferably from 150 to 600 mg, more preferably from 300 to 600 mg, most preferably it is 300 mg.

The invention is illustrated further by the following examples.

Examples

The following abbreviations were used:

os = oral supplementation

5

Example 1: Study**Study design**

double blind, randomized, placebo-controlled, cross over study, single center

10

Study population and planned sample size

12 healthy male volunteers (age 18-40, Body Mass Index 27 - 35), each volunteer underwent five experiments (A to E).

15 **Study supplement**

Hard-gelatin capsules with 300 mg EGCG, hard-gelatin capsules with 150 mg EGCG, hard-gelatin capsules with 100 mg caffeine, hard-gelatin capsules with 150 mg EGCG + 100 mg caffeine or hard-gelatin capsules with with placebo, twice a day.

20 **Dosage regime****Experiment A**

150 mg EGCG, one capsule, twice per day per os for two days;

300 mg EGCG, two capsules, prior basal and 150 mg EGCG, one capsule, prior to post-

25 prandial measurement.

Experiment B

300 mg EGCG, one capsule, twice per day per os for two days;

600 mg EGCG, two capsules, prior basal and 300 mg EGCG, one capsule, prior to post-

30 prandial measurement

Experiment C

100 mg caffeine, one capsule, twice per day per os for two days;

200 mg caffeine, two capsules, prior basal and 100 mg caffeine, one capsule, prior to post-prandial measurement.

Experiment D

- 5 150 mg EGCG + 100 mg caffeine, one capsule, twice per day per os for two days;
300 mg EGCG + 200 mg caffeine, two capsules, prior basal and 150 mg EGCG + 100 mg caffeine, one capsule, post-prandial measurement.

Experiment E

- 10 placebo, one capsule, twice per day per os for two days;
two capsules, prior basal and one capsule prior to post-prandial measurement.

The study supplements were taken orally twice daily, 1.0 hours before breakfast and dinner, respectively for which specific nutritional guidelines had to be followed.

15

Duration of treatment

The supplementation lasted 3 days for each experiment, each supplementation was separated by ≥ 1 week.

20 **Parameters**

- Fat oxidation, glucose oxidation, and thermogenesis by indirect calorimetry protein oxidation by urinary N-excretion
- EGCG and caffeine profile
- Vital signs (BP, HR)
- 25 ➤ Clinical chemistry
- Blood glucose and insulin level
- Adverse event reporting

Study procedures

- 30 The recruitment and screening of volunteers (Visit 0) involved two stages:
1. The study procedures were explained. Screening consent was obtained. Medical history, general health, body composition, physical activity and food intake was assessed.

2. Determination of eligibility/inclusion: Eligibility was determined once all results including clinical laboratory were available. Volunteers signed the informed consent for the study and were randomly assigned to the five experiments (A, B, C, D, and E).

- 5 The volunteers were instructed to maintain their normal dietary habits. There was no excess physical activity 24 hours prior to the study.

The study procedures were performed at the different visits V1 – V5.

Volunteers were then given their capsules and the respective instructions.

- 10 Twice daily, over 3 days, volunteers received one capsule containing either 150 mg EGCG (group A), 300 mg EGCG (group B), 100 mg caffeine (group C), 150 mg EGCG + 100 mg caffeine (group D), or placebo (group E). All capsules had identical appearance. During this period, subjects drank no caffeine containing beverages.

- 15 At day 2, volunteers spent the night at the hospital. At day 3, 1.0 hours prior to basal measurements, volunteers received the daily dose of supplementation. 1.0 hours before the study meal volunteers received half of the daily dose of supplementation.

- For completion of all tests and measurements at the different clinical visits a period of 7
20 days was not exceeded.

Statistical considerations

- The main parameter (fat oxidation) was tested with analysis of variance: variable was treatment (EGCG, caffeine, placebo). Pairwise comparison across treatments was per-
25 formed by using t-test with bonferroni's correction. A p-value smaller than 0.05 was considered significant. Values are given as mean $\pm$ SD. Graphical displays were generated. If a numeric and/or statistical analysis was not possible a descriptive analysis was done.

- In the following figures the “*” indicates a statistical significance between treatment and
30 placebo, whereas “p” represents the probability that an observed difference between the intervention and control groups is due to chance alone if the null hypothesis is true. A p-value of 0.05 or less rejects the null hypothesis "at the 5% level", i.e. the statistical assumptions used imply that only 5% of the time the supposed statistical process would pro-

duce a finding this extreme that the null hypothesis is true. 5% and 10% are common significance levels to which p-values are compared.

5 In all figures the following correlation applies:

 group A;  group B;  group C;  group D;  group E.

Figure 1: Respiratory Quotient (RQ)

10 X = delta in Respiratory Quotient; y1 = basal, y2 = post prandial

Fig. 1 shows the difference in the respiratory quotient of the groups A to D in comparison to group E. The respiratory quotient was assessed by indirect calorimetry using a Deltatrac. In group A, C and D the respiratory quotient was reduced in comparison to group E during
15 basal conditions. During post prandial conditions these differences were still existing or even increased. Furthermore, during post prandial conditions the respiratory quotient was also different between group B and group E.

Figure 2: Lipid oxidation (Lox) rate

20 X = delta lipid oxidation g/4h; y1 = basal, y2 = post prandial

Fig. 2 shows the difference in the lipid oxidation rate of the groups A to D in comparison to group E. The lipid oxidation rate was assessed by indirect calorimetry using a Deltatrac. In group A, B, C and D the lipid oxidation rate was increased in comparison to group E
25 during basal conditions. During post prandial conditions these differences were more pronounced. Statistical significance was observed for group C and D during basal conditions and for group D at post prandial conditions.

Figure 3: Carbohydrate oxidation rate (Cox)

30 X = delta carbohydrate oxidation g/4h; y1 = basal, y2 = post prandial

Fig. 3 shows the difference in the carbohydrate oxidation rate of the groups A to D in comparison to group E. The carbohydrate oxidation rate was assessed by indirect calorimetry using a Deltatrac. In group A, B, C and D the carbohydrate oxidation rate was reduced in

comparison to group E during basal conditions. During post prandial conditions these differences were more pronounced. Statistical significance was observed for group D during prandial conditions.

5 **Figure 4: Increase in postprandial lipid oxidation rate, relative to basal**

X = delta between basal and post prandial lipid oxidation g/4h; y1 = basal, y2 = post prandial

Fig. 4 shows the increase in the lipid oxidation rate of the groups A to D relative to group
10 E between basal and post prandial conditions. The lipid oxidation rate was assessed by indirect calorimetry using a Deltatrac. There was an increase in lipid oxidation rate from basal to post prandial conditions in group A, B, and C, whereas it was highest in group A. No change was observed for group D.

15 **Figure 5: Lipid oxidation rate during maximum post prandial stimulation**

X = g/h; y = maximum post prandial stimulation (80 Min after the meal)

Fig. 5 shows the lipid oxidation rate of the groups A, C, D and E during maximum post prandial stimulation due to the test meal. The lipid oxidation rate was assessed by indirect
20 calorimetry using a Deltatrac. Lipid oxidation rate increased in group A, C, D, and E, whereas the lipid oxidation rate of group A, C and D were higher compared to group E,

Figure 6: Synergism between EGCG and Caffeine on fat oxidation

X = Difference in fat oxidation vs. Placebo at maximal stimulation g/h; y = maximum post
25 prandial stimulation (80 minutes after the meal)

Fig. 6 shows the synergism between groups A and C on fat oxidation during maximum post prandial stimulation. The lipid oxidation rate was assessed by indirect calorimetry using a Deltatrac. Group D has higher lipid oxidation than the sum of group A and group C,
30 suggesting a synergism.

Figure 7: Changes in Energy Expenditure (EE) vs. placebo

X = delta EE kJ/min; y1 = basal, y2 = post prandial

Fig. 7 shows the difference in energy expenditure of the groups A to D in comparison to group E. Energy expenditure was assessed by indirect calorimetry using a Deltatrac. In groups A, B, and C energy expenditure was hardly changed, but there was a trend of slight reduction, whereas in group D it was unchanged in comparison to group E during basal conditions. During post prandial conditions these differences were blurred. Except for group C which showed increased energy expenditure during post prandial conditions.

Figure 8: TEAVIGO™ improves flow mediated dilation

X = Changes in FMD vs. baseline (%); y1 = acute, y2 = chronic

10

Fig. 8 shows the difference in flow mediated dilation (FMD) of the groups A and E in comparison to baseline for acute (2 hours), and chronic (2 weeks) treatment. Flow mediated dilation was assessed by using ultrasound. In groups A, and E, flow mediated dilation was acutely increased compared to baseline. For chronic conditions the increases for both groups were blunted.

15

Figure 9: Plasma levels after TEAVIGO™ supplementation

X = Changes in plasma EGCG vs. baseline (%), baseline (%); y1 = acute, y2 = chronic

Fig. 9 shows the difference in EGCG plasma levels the groups A and E in comparison to baseline for acute (2 hours), and chronic (2 weeks) treatment. EGCG in plasma was determined by High Performance Liquid Chromatography-Mass Spectrometry. In group A, EGCG levels were increased after acute administration. There was no change in group E after acute administration. The same is seen for group E after chronic treatment. The plasma EGCG level returned to baseline after chronic treatment. This is due to assessing the EGCG level 14 hours after the last administration. Therefore, EGCG does not accumulate in plasma.

20

25

Figure 10: Lipid oxidation rate

X = lipid oxidation g/4h; y1 = basal, y2 = post prandial

30

Fig. 10 shows the lipid oxidation rate of the groups A to E. The lipid oxidation rate was assessed by indirect calorimetry using a Deltatrac. In all groups the lipid oxidation rate is higher during basal conditions compared to post prandial conditions. Between groups, lipid

oxidation rate in group E is lowest under the respective condition. Statistical significance was observed for group C and D during basal conditions and for group D at post prandial conditions.

5 **Figure 11: Carbohydrate oxidation rate**

X = carbohydrate oxidation g/4h; y1 = basal, y2 = post prandial

Fig. 11 shows the carbohydrate oxidation rate of the groups A to E. The carbohydrate oxidation rate was assessed by indirect calorimetry using a Deltatrac. In all groups the carbohydrate oxidation rate is higher during post prandial conditions compared to basal conditions. Between groups, carbohydrate oxidation rate in group E is highest under the respective condition. Statistical significance was observed for group D during post prandial.

Claims

1. Use of a dietary supplement containing (–)-epigallocatechin gallate for increasing the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and
5 horses, whereby the dietary supplement is incorporated by said mammal **before** the regular intake of food, feed or beverages containing said fat whose oxidation is increased.
2. Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the weight of a mammal selected from the group consisting of humans, cats, dogs and horses,
10 whereby the dietary supplement is incorporated by said mammal **before** the intake of food, feed or beverages.
3. Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses,
15 whereby the dietary supplement is incorporated by said mammal **before** the intake of food, feed or beverages.
4. Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats,
20 dogs and horses, whereby the dietary supplement is incorporated by said mammal **before** the regular intake of food, feed or beverages containing said carbohydrate whose oxidation is reduced.
5. The use according to any one of claims 1 to 4, wherein the dietary supplement is incor-
25 porated by said mammal at least half an hour **before** the intake of food, feed or beverages.
6. The use according to any one of claims 1 to 4, wherein the dietary supplement is incor-
porated by said mammal at a point in time between half an hour and one and a half hour
before the intake of food, feed or beverages.
- 30 7. Use of a dietary supplement containing (–)-epigallocatechin gallate for increasing the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal **simultaneously**

with the regular intake of food, feed or beverages containing said fat whose oxidation is increased.

8. Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the weight of a mammal selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal **simultaneously** with the intake of food, feed or beverages.
9. Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal **simultaneously** with the intake of food, feed or beverages.
10. Use of a dietary supplement containing (–)-epigallocatechin gallate for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, whereby the dietary supplement is incorporated by said mammal **simultaneously** with the regular intake of food, feed or beverages containing said carbohydrate whose oxidation is reduced.
11. Use of a food, feed or beverage fortified with (–)-epigallocatechin gallate for increasing the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and horses.
12. Use of a food, feed or beverage fortified with (–)-epigallocatechin gallate for reducing the weight of a mammal selected from the group consisting of humans, cats, dogs and horses.
13. Use of a food, feed or beverage fortified with (–)-epigallocatechin gallate for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses.
14. Use of a food, feed or beverage fortified with (–)-epigallocatechin gallate for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats, dogs and horses.

15. Use of (–)-epigallocatechin gallate, preferably in combination with a sympathomimeticum, (for the manufacture of a composition) for reducing the respiratory quotient in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in
5 humans.

16. Use of (–)-epigallocatechin gallate (for the manufacture of a composition) for improving the flow mediated dilation, thereby contributing to the beneficial effects on coronary heart, in mammals selected from the group consisting of humans, cats, dogs and horses,
10 preferably in humans.

17. Use of (–)-epigallocatechin gallate, preferably in combination with a sympathomimeticum, (for the manufacture of a composition) for supporting the metabolism of fat in mammals selected from the group consisting of humans, cats, dogs and horses, preferably
15 in humans, wherein the (–)-epigallocatechin gallate is administered in such a way that it is present in the body during the intake of food/feed/beverages of the mammal selected from the group consisting of humans, cats, dogs and horses, preferably of the human, preferably that it is present in a high concentration in the body during the intake of food/feed/beverages of the mammal selected from the group consisting of humans, cats,
20 dogs and horses, preferably of the human.

18. Use of (–)-epigallocatechin gallate, preferably in combination with a sympathomimeticum, (for the manufacture of a composition) for increasing the endurance in mammals selected from the group consisting of humans, cats, dogs and horses, preferably for increasing the endurance in humans.
25

19. The use according to claim 18, wherein the (–)-epigallocatechin gallate is administered in such a way that it is present, preferably in high concentration, in the body when the mammal selected from the group consisting of humans, cats, dogs and horses, preferably
30 when the human, is performing the activity for which endurance is needed.

20. Use of (–)-epigallocatechin gallate, preferably in combination with a sympathomimeticum, for the manufacture of a composition for supporting the metabolism of fat in mammals selected from the group consisting of humans, cats, dogs and horses, preferably

in humans, wherein the composition is administered in such a way that (–)-epigallocatechin gallate is present in the body during the intake of food/feed/beverages of said mammal, preferably that it is present in a high concentration in the body during the intake of food/feed/beverages of said mammal.

5

21. The use according to any of claims 1 to 20, wherein the daily dosage of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight, preferably from 2.0 to 9 mg per kg body weight, more preferably from 4.0 to 9.0 mg per kg body weight, most preferably from 4.0 to 4.5 mg per kg body weight.

10

22. The use according to any of the claims 1 to 21, wherein the (–)-epigallocatechin gallate has a purity of at least 80%, preferably of at least 85%, more preferably of at least 90%.

23. The use according to any of the claims 15, 17, 18 and 20, wherein the sympathomimeticum is caffeine.

15

24. The use according to any of the claims 15 to 23, wherein the (–)-epigallocatechin gallate is in a form selected from the group consisting of (fortified) food or (fortified) feed, dietary supplements, beverages, tablets, granules, capsules, pastes, food additives, feed additives, and effervescent formulations.

20

25. The use according to any of the claims 1 to 24, wherein the daily dosage of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight, preferably from 2.0 to 9 mg per kg body weight, more preferably from 4.0 to 9.0 mg per kg body weight, most preferably from 4.0 to 4.5 mg per kg body weight.

25

26. A method for increasing the fat oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of (–)-epigallocatechin gallate, preferably in combination with an effective dose of a sympathomimeticum, to said mammal which is in need thereof before the intake of food, feed or beverage, containing said fat whose oxidation is increased, by said mammal, characterized in that the effective dose of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg

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per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

27. A method for supporting the metabolism of fat in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of (–)-epigallocatechin gallate, preferably in combination with an effective dose of a sympathomimeticum, to said mammal which is in need thereof before the intake of food, feed or beverage by said mammal, characterized in that the effective dose of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

28. The method according to claim 26 or 27, wherein the (–)-epigallocatechin gallate is administered in such a way that it is present in a high concentration in the body during the intake of food/feed/beverages of said mammal.

29. A method for reducing the fat mass in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of (–)-epigallocatechin gallate, preferably in combination with a sympathomimeticum, to said mammal which is in need thereof before the intake of food, feed or beverage by said mammal, characterized in that the effective dose of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

30. A method for reducing the weight of mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of (–)-epigallocatechin gallate, preferably in combination with a sympathomimeticum, to said mammal which is in need thereof before the intake of food, feed or beverage by said mammal, characterized in that the effective dose of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

31. A method for reducing the carbohydrate oxidation in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of (–)-epigallocatechin gallate, preferably in
5 combination with a sympathomimeticum, to said mammal which is in need thereof before the intake of food, feed or beverage, containing said carbohydrate whose oxidation is reduced, by said mammal, characterized in that the effective dose of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per
10 day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

32. The method according to any of the claims 26 to 31, further comprising the step of said mammal performing physical activity.

15 33. A method for increasing the endurance in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising the step of administering an effective dose of (–)-epigallocatechin gallate, preferably in combination with a sympathomimeticum, to said mammal which is in need thereof, characterized in that the effective dose of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg
20 body weight per day, preferably from 2.0 to 9 mg per kg body weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

34. The method according to claim 33, wherein the (–)-epigallocatechin gallate is administered in such a way that it is present, preferably in a high concentration, in the body when
25 said mammal is performing the activity for which endurance is needed.

35. A method for reducing the respiratory quotient in mammals selected from the group consisting of humans, cats, dogs and horses, preferably in humans, said method comprising
30 the step of administering an effective dose of (–)-epigallocatechin gallate, preferably in combination with a sympathomimeticum, to said mammal which is in need thereof, characterized in that the effective dose of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body weight per day,

more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

36. A method for improving the flow mediated dilation in mammals selected from the
5 group consisting of humans, cats, dogs and horses, preferably in humans, thereby contributing to a beneficial effect on the coronary health, said method comprising the step of administering an effective dose of (–)-epigallocatechin gallate to said mammal which is in need thereof, characterized in that the effective dose of (–)-epigallocatechin gallate varies from 0.14 to 25 mg per kg body weight per day, preferably from 2.0 to 9 mg per kg body
10 weight per day, more preferably from 4.0 to 9.0 mg per kg body weight per day, most preferably from 4.0 to 4.5 mg per kg body weight per day.

37. The method according to any of the claims 26 to 36, wherein the mammals are humans with a body mass index above 25.

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38. The method according to any of the claims 26 to 37, wherein the (–)-epigallocatechin gallate has a purity of at least 80%, preferably of at least 85%, more preferably of at least 90%.

20 39. Sport beverages containing (–)-epigallocatechin gallate, preferably (–)-epigallocatechin gallate with a purity of at least 80%.

Figure 1

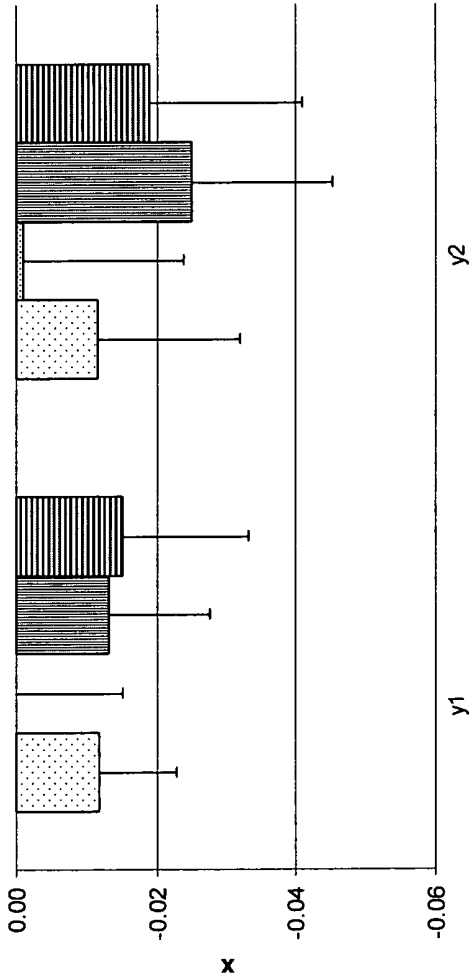


Figure 2

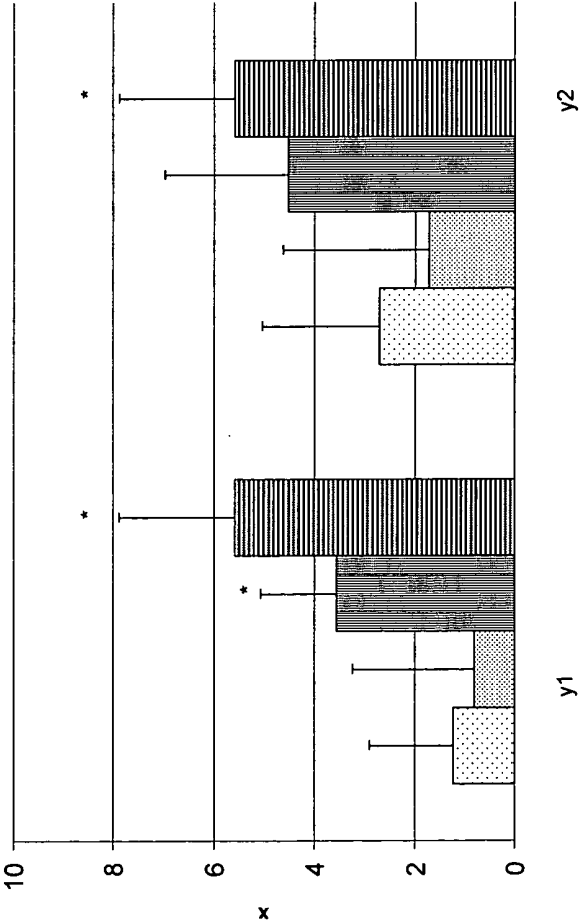


Figure 3

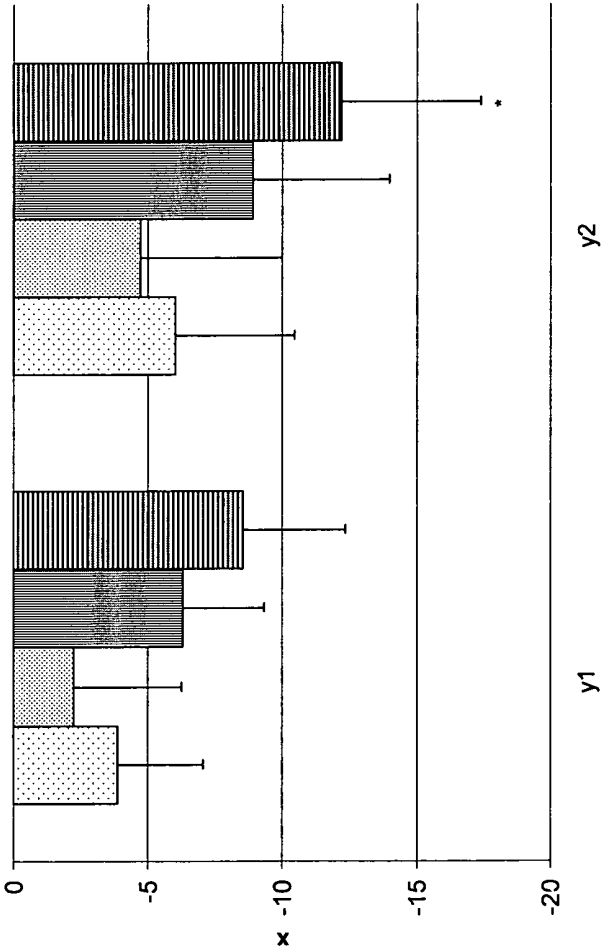


Figure 4

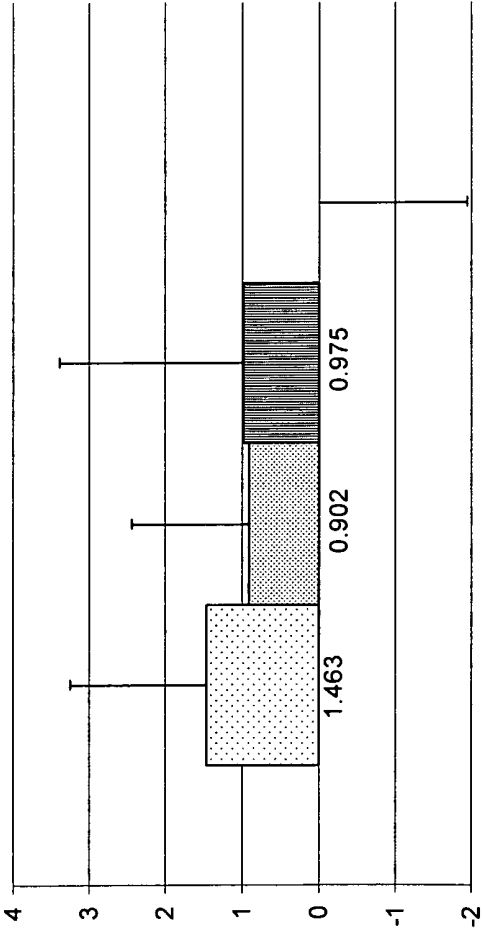


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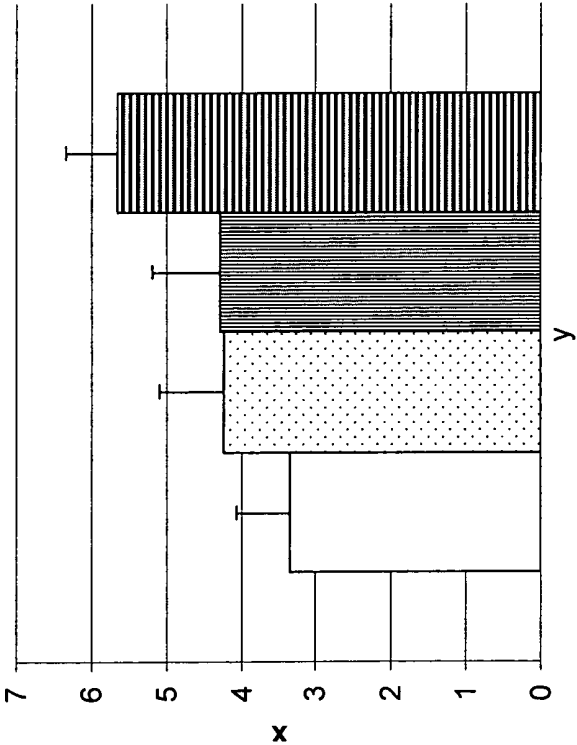


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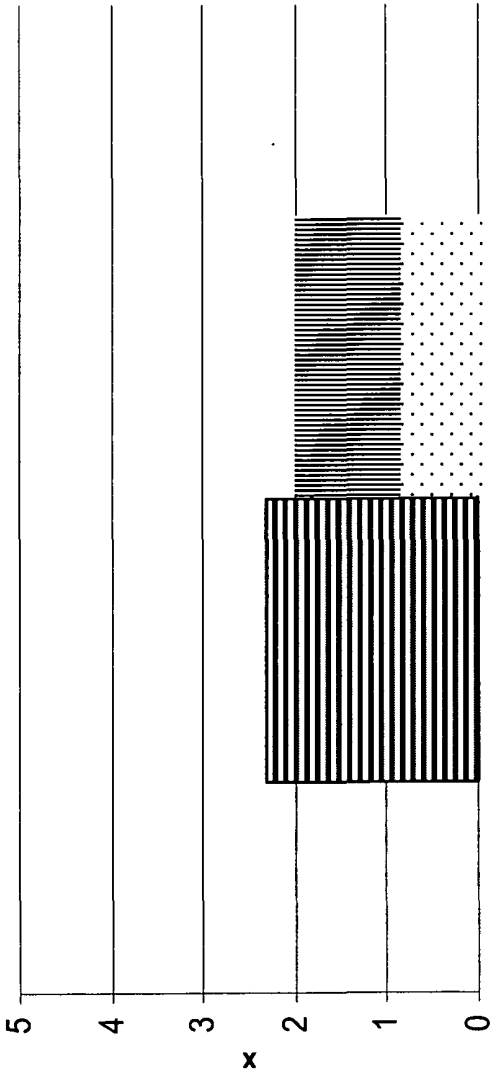


Figure 7

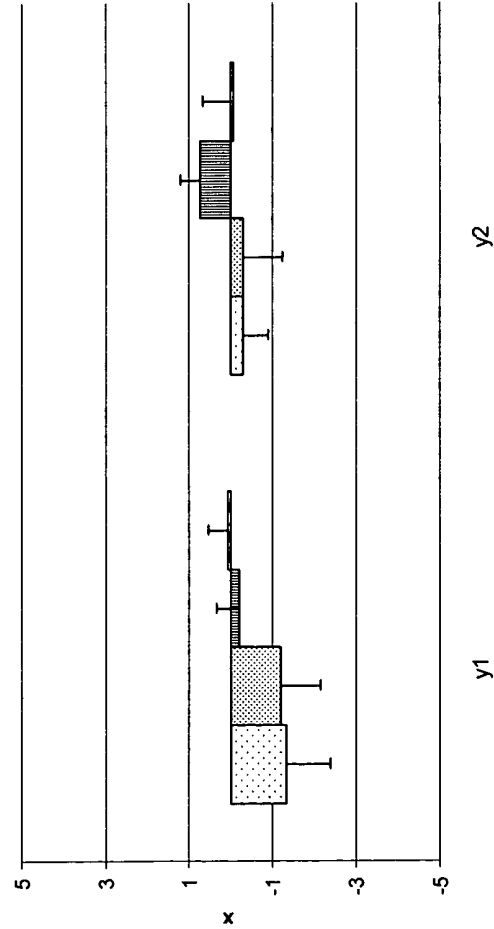
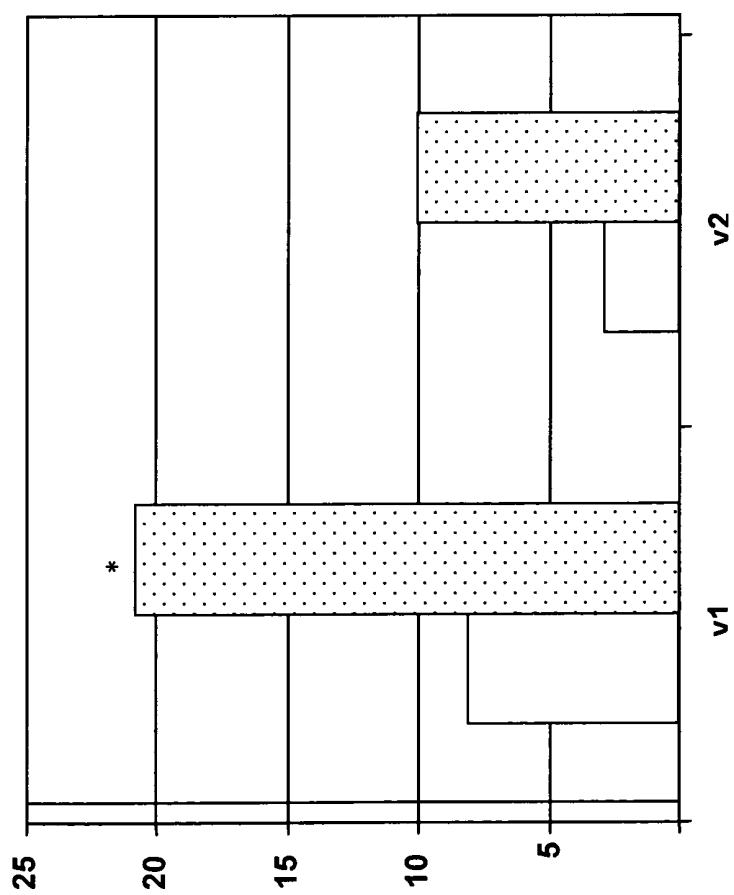


Figure 8



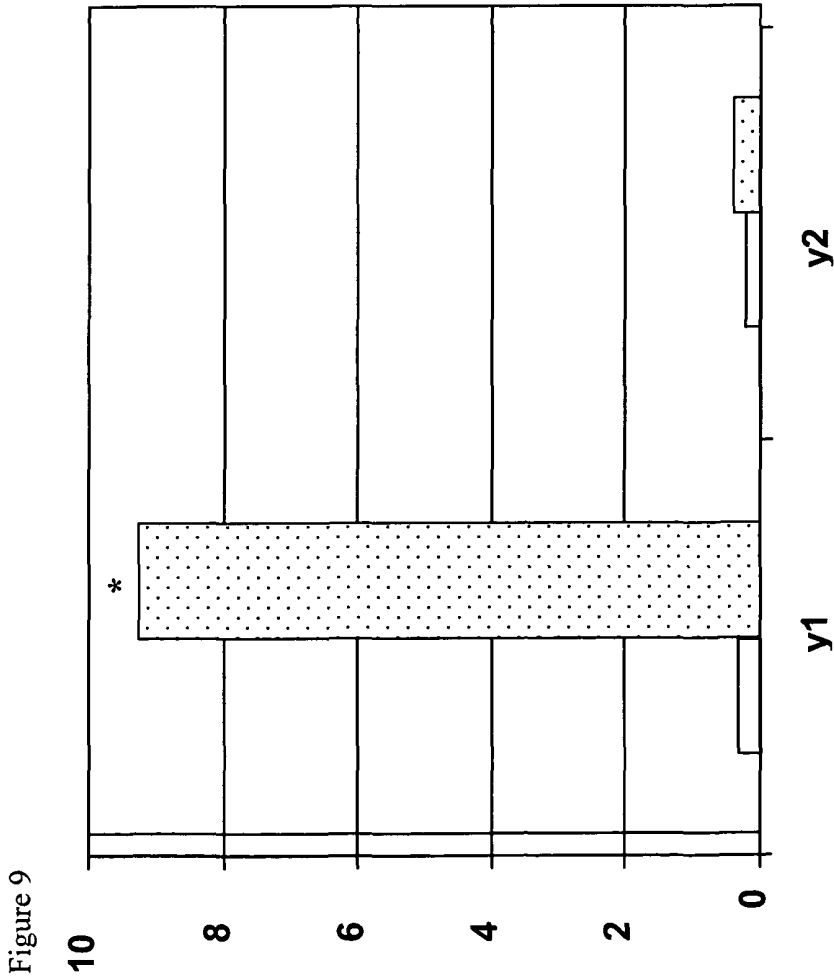


Figure 10

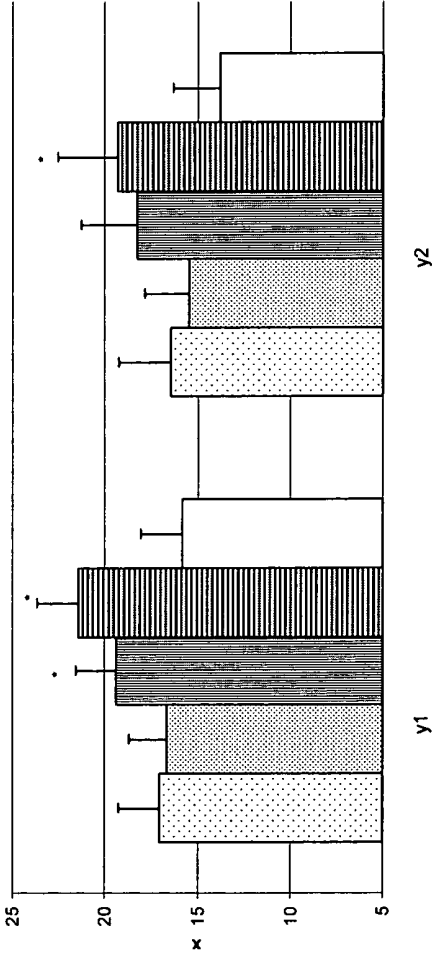


Figure 11

