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[54]	Title:	WHITENING SUPPLEMENT WITH PROBIOTICS	
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[57]	Abstract:	The invention is a skin whitening supplement containing Probiotic culture. Probiotics are beneficial for human health for it facilitate proper absorption of vitamins, minerals, nutrients and other ingredients in the formulation. Probiotics also aid in improving the skin's condition. The formula is a combination of a Probiotic culture and five potent active ingredients in beauty and whitening. The four potent antioxidants for whitening are: Glutathione-reduced, N-Acetyl Cysteine, Alpha Lipoic Acid and Sodium Ascorbate. Collagen, a major structural protein of the skin, was added to keep the skin healthy. The Probiotic culture in the formulation is the patented strain of Lactobacillus casei KE-99, validated and proven to be effective probiotic compared to other strains. The six active ingredients are combined in one as a whitening supplement for an easy consumption in a vegetable source hydroxylpropyl methylcellulose capsule, or as tablets and even in a powder form.	

WHITENING SUPPLEMENT

WITH PROBIOTICS

FIELD OF THE INVENTION

The invention relates to a skin whitening supplement which has Probiotics to
5 increase absorption of vitamins, mineral, and nutrients and aid in improving skin's
condition.

ABSTRACT OF THE DISCLOSURE

The invention is a skin whitening supplement containing Probiotic culture.
Probiotics are beneficial for human health for it facilitate proper absorption of vitamins,
10 minerals, nutrients and other ingredients in the formulation. Probiotics also aid in
improving the skin's condition. The formula is a combination of a Probiotic culture and
five potent active ingredients in beauty and whitening. The four potent antioxidants for
whitening are: Glutathione-reduced, N-Acetyl Cysteine, Alpha Lipoic Acid and Sodium
Ascorbate. Collagen, a major structural protein of the skin, was added to keep the skin
15 healthy. The Probiotic culture in the formulation is the patented strain of *Lactobacillus*
casei KE-99, validated and proven to be effective probiotic compared to other strains.
The six active ingredients are combined in one as a whitening supplement for an easy
consumption in a vegetable source hydroxylpropyl methylcellulose capsule, or as tablets
and even in a powder form.

20 BACKGROUND OF THE INVENTION

Whitening products are widely available in different forms all over the world.
This invention is a new concept for it has a revolutionary combination of a probiotics,
collagen and four potent antioxidants such as Glutathione- reduced, N-Acetyl Cysteine,
Alpha Lipoic Acid and Sodium Ascorbate.

World Health Organization and Food and Agriculture Organization of the United Nations define Probiotics as “live microorganisms, which, when administered in adequate amounts, confer a health benefit on the host.”

Based on studies, gut microbial balance and oral probiotics have the ability to influence systemic inflammation, oxidative stress, even mood itself that may have an important implications in the skin’s condition. Stoke and Pillsbury presented a theoretical and practical consideration of a gastrointestinal mechanism wherein the skin is influenced by emotional and nervous states. The two authors discussed emotional states such as depression, worry and anxiety can alter gastrointestinal tract function, changes that cause alterations to the microbial flora, which they theorized, in turn promotes local and systemic inflammation.

Oral Probiotics are good bacteria that are inhabitants of the intestinal tract, which beneficially affect the host by improving the intestinal microbial balance and helps in digestion and facilitate proper absorption of vitamins, mineral and other nutrients in the whitening supplement like Glutathione-reduced, N-acetyl-Cysteine, Alpha lipoic acid, Collagen Peptide and Sodium Ascorbate.

The probiotic in this invention is the patented subspecies of *Lactobacillus casei* (*Lactobacillus casei* KE-99), evaluated at a public university in California and had proven to have superior absorption and functionality as a probiotic as compared to other strains.

Glutathione-reduced, a powerful anti-oxidant, which plays a vital role in supporting cellular function such as detoxification, amino acid transport, production of co-enzymes and recycling of Vitamin C & Vitamin E. It protects the body by destroying reactive oxygen and free radicals. It inhibits the activity of tyrosine and production of melanin and helps prevent peroxy lipid generation by scavenging reactive oxygen.

N-Acetyl-Cysteine, (NAC) also a powerful antioxidant, a precursor of glutathione (GSH). It increases the level of glutathione in the body that can help replenish intracellular levels of GSH. Once NAC enters the body, it is metabolized into glutathione.

Alpha Lipoic acid, the “universal antioxidant”, prevents certain kind of cell damage in the body. It has a distinct characteristic of being water and fat-soluble. It also functions in revitalizing the underlying structure of the skin to keep it healthy.

Collagen Peptide is one of the most important structural components in the body. It works as a binder to combine one cell with another, and to facilitate transfer of nutrients.

Sodium Ascorbate is an antioxidant which is essential to synthesize collagen. It is
5 a more bioavailable form that also contains antibacterial and antiviral properties to help the body fight infections, boosting the immune response.

SUMMARY OF THE INVENTION

This invention provides a whitening supplement in a capsule that combines Probiotics, which is beneficial for human health, with five potent active ingredients in
10 whitening and beauty. The five active ingredients are: Glutathione- reduced, N-Acetyl Cysteine, Alpha Lipoic Acid, Sodium Ascorbate and Collagen. The Probiotic culture is the strain of *Lactobacillus casei* KE-99 which is validated and proven to be effective.

DETAILED DESCRIPTION

To address the demand if the cosmeceutical industry for a better whitening product, we have designed and tested a new class of dietary supplements (nutritional supplements for oral consumption). The formulation contains four potent antioxidants:

- 5 i) Glutathione- reduced, ii) N-Acetyl Cysteine, iii) Alpha Lipoic Acid, iv) Sodium Ascorbate, a major structural protein in the skin, Collagen, and a special strain of *Lactobacillus casei* as a probiotic culture. The six active ingredients are combined for an easy consumption in vegetable source hydroxypropyl methylcellulose capsule, or as tablets and even in a powder form.

- 10 Each of the six ingredients confer dietary benefits on their own, as described below, allowing the consumer to get multiple and complete benefits in the convenience of a single product.

- It is a hypothesis of this invention that the ingredients also work together synergistically in a manner that powerfully enhances each other's activity, thus promoting
15 each other's activity. The whitening formulation is said to be absorbed better through the gastrointestinal health enhancing capability of the probiotics.

The Clinical Trial detailed in Example 1 (Attach the Clinical Trial FINAL) that the dietary supplement is safe and also has the potential to provide essential benefits.

PROBIOTICS

- 20 The dietary supplement of this invention is a whitening formula containing probiotics. These are microorganisms, particularly bacteria or yeast that (as defined by World Health Organization) have the potential to confer a health benefit to the host when administered in adequate amounts.

- Health benefits of probiotics are well established. Their primary effect is to restore
25 balance to the micro flora in the gastrointestinal tract. Direct benefits of this include improved regularity and less gas. Probiotics are also thought to strengthen the immune system to combat allergies, and alleviate diseases. Probiotics also promote better digestion and a healthy gut function thus improving metabolism and absorption of vitamins, minerals, and nutrients. It is also a hypothesis of this invention that (in

conjunction with the 5 active whitening and skin improving adjunct ingredients in the dietary supplement), probiotics are beneficial for the skin.

The term "probiotic culture" as used in this disclosure refers to a plurality of probiotic microorganisms that (upon suspension or reconstitution in a suitable growth
5 medium) will create a proliferating and sustainable source of live cells. Typically, the probiotic culture is not growing while in the dietary supplement, but has been freeze-dried or otherwise preserved in a manner that enables it to be reconstituted in the laboratory or in the gastrointestinal tract into a growing cell population.

Probiotics organisms that may be suitable for use in this invention include
10 *Bifidobacterium bifidum*, *B. breve*, *B. infantis*, *B. longum*, *Lactobacillus acidophilus*,
L. brevis, *L. bulgaricus*, *L. casei*, *L. paracasei*, *L. plantarum*, *L. rhamnosus*, *L. salivarys*,
L. lactis, *Streptococcus thermophiles* and *Saccharomyces boulardii*,

Exemplary is the *L. Casei* strain KE-99 (also designated as KE-01) available from
the American Type Culture (ATCC), 10801 University Blvd. Manassas VA 20110, USA,
15 under Accession No. PTA-3945. The strain is protected by US Patent number 6,797,266.

The KE-99 strain was selected from traditional fermented yogurt-like Asian dairy
products with at least 10-year history of safe human consumption. The strain was
identified as having the following characteristics: i) resistance to low pancreatic juice
ii) adherence ability to sub-epithelial matrices iii) an ability completely exclude
20 enterohemorrhagic *e.coli* serotype O157:H7 adherent to collagen matrices; and iv) a
capacity to reduce ammonia and sulfide containing compounds.

KE-99 can be grown in a suitable nutrient medium (such as *Lactobacillus* MRS
broth from Difco). To prepare a freeze-dried powder, typically in a mixture of carriers
containing anhydrous dextrose and trehalose.

25 WHITENING ACTIVE INGREDIENTS

GLUTATHIONE-REDUCED (GSH)

The dietary supplement in this invention contains a powerful antioxidant, which is
a tri-peptide composed of glutamic acid, cysteine and glycine, which plays a vital role in
supporting cellular function such as detoxification, amino acid transport, production of
30 co-enzymes and recycling of Vitamin C and E.

It inhibits the activity of tyrosinase and production of melanin, which helps to prevent peroxy lipid generation by scavenging reactive oxygen.

The reduced form is the readily bioavailable form.

N-ACETYL-CYSTEINE (NAC)

- 5 The dietary supplement in this invention contains a powerful antioxidant, N-Acetyl-Cysteine which is also a precursor to the tri-peptide, Glutathione. It is derived from the amino acid, cysteine. These antioxidants blocks free radicals and can readily enter the cells. It increases the level of glutathione n the body that can help replenish intracellular levels of GSH. Once NAC enters the body, it is metabolized into glutathione.
- 10 It also prevents alcoholic liver damage.

NAC also support body's immune system and colon health.

ALPHA LIPOIC ACID (ALA)

- The dietary supplement in this invention contains the "universal antioxidant," Alpha Lipoic Acid. It has the ability to exert in water or oil based environments which
- 15 enables it to deliver antioxidant benefits anywhere in the body. Scientists believe that ALA operates in conjunction with Vitamins C, E, and glutathione, recycling them when they're used up.

ALA is a substance that attacks free radicals.

COLLAGEN PEPTIDE

- 20 The dietary supplement in this invention contains Collagen, which is a major structural protein in the skin. It makes up 75% of our skin and gives its strength and durability. It is responsible for the younger appearance of the skin. In our body, collagen works as a binder to combine one cell with another to transfer water and nutrients.

SODIUM ASCORBATE

- 25 The dietary supplement in this invention contains an antioxidant, Sodium Ascorbate. It is essential to synthesize collagen. This salt is in a more bioavailable form. It helps the body fight infections, boosting the immune response.

SYNERGIES

Besides their direct and independent benefits, the active ingredients of the dietary supplement in this invention are believed to work together synergistically in a manner that powerfully enhances each other's activity, thus promoting the beneficial effects.

- 5 Taken individually, they exert beneficial effects to the skin. The addition of the probiotics, *Lactobacillus casei* KE-99 enhances their absorption and utilization.

Ways the components are believed to act synergistically include the following: The probiotic culture can improve gastrointestinal health and function, which in turn is believed to improve absorption of vitamins, minerals, amino acids, nutrients and active
10 ingredients, thereby boosting their dermatological effects. The probiotic microorganisms also generate arylamidases: Oakey HJ, Harty DWA, Knox KW, J. Apl. Bacteriology 1995; 78:142-148. Arylamidases are protein-digesting enzymes that may help break down small peptides in the hydrolyzed collagen and other protein, improving absorption and subsequent processing.

- 15 Conversely, the collagen in the formulation of this dietary supplement is believed to have a prebiotic effect, supporting the probiotic culture. The antioxidants in the formula namely: Glutathione-reduced, N-Acetyl Cysteine, Alpha Lipoc Acid, and Sodium Ascorbate, may help keep the probiotic bacteria in quiescent state, and otherwise help prevent spoilage, thereby improving long-term stability and storage of the combined
20 dietary supplement

COMPOUNDING

The dietary supplement in this invention is formulated by combining potent antioxidant, whitening ingredients and the absorption enhancing capability of probiotics.

- By way of illustration, freeze-dried *L. casei* KE-99 can be combined with USP
25 Grades Glutathione-reduced, N-Acetyl-Cystein, Alpha Lipoic acid, Sodium Ascorbate, and Collagen Peptide.

In the usual process of manufacture, each of the sources is sufficiently concentrated to yield a product that enables the consumer to receive benefits of all the active ingredients in a daily dose. The supplement contains 5 Billion CFU (Colony
30 Forming Unit), 215 mg of N-Acetyl-Cysteine, 100 mg of Glutathione-reduced, 100 mg of Collagen Peptide, 50 mg Alpha Lipoic Acid, and 10 mg of Sodium Ascorbate.

The manufacturer can supply the dietary supplement in the form of capsules, tablets, or powder.

One or more week's or month's supply of any of these dosage forms can be packaged in suitable container for commercial distribution. The package may have
5 (or may be distributed in conjunction with) written information about consumption of the product or possible use of the product to improve skin health or appearance.

Dietary supplements are produced in compliance with the requirements of regulatory authorities for the jurisdiction in which they will be distributed, FDA for the Philippines.

10 USE

The dietary supplement in this invention may be consumed or prescribed in any amount or frequency that the user determines is appropriate. For adults (18-50 years of age) the typical dose is 1-4 capsules/ day.

This supplement has been designed primarily with a view of consumption by
15 human subjects. Veterinary use may also be feasible, incorporating adaptations in formulation and dosage where appropriate.

Probiotic bacteria and other microorganisms in a dietary supplement of this invention may improve the balance of microflora in the gut, thereby benefiting the gastrointestinal system in terms of health and function. Example 1 shows that the dietary
20 supplement can be used to reduce intestinal gas, increase regularity, and otherwise assist in reduction of gastrointestinal upset.

Example 1 also demonstrated that the dietary supplements of this invention are safe, and have a potential to improve characteristics of facial skin. Regular consumption of such supplements will improve skin condition to be fairer and younger looking.

25 EXAMPLES (PLEASE SEE CLINICAL TRIAL DATA ATTACHED)

CLAIMS

1 A whitening supplement composition comprising of Probiotics, Collagen and four potent antioxidants, wherein the four antioxidants are present in an amount effective for skin whitening and work synergistically in a manner that powerfully enhances each other's activity as a whitening supplement.

2 The composition of claim 1 wherein the Probiotics is the strain of patented subspecies of *Lactobacillus casei* (*Lactobacillus casei* KE-99), when administered in adequate amounts, confer a health benefit on human health.

3 The composition of claim 1 wherein the Collagen is in the form of Collagen peptide, a major structural protein in the skin, works as a binder to combine one cell with another to transfer water and nutrients.

4 The composition of claim 1 wherein the four antioxidants are Glutathione, N-acetyl cysteine, Alpha lipoic acid and Sodium Ascorbate, synergistically combined to increase skin-whitening efficacy of each antioxidant.

5 The composition of claim 5 wherein the Glutathione is in reduced form, the most bioavailable form of Glutathione which has an inhibitory activity against tyrosinase and melanin synthesis, helps to prevent peroxy lipid generation by scavenging reactive oxygen.

6 The composition of claim 5 wherein N-acetyl cysteine and Alpha Lipoic Acid are precursors of Glutathione, both increase the level of glutathione in the body that can help replenish intracellular levels of GSH.

7 The composition of claim 5 wherein N-acetyl cysteine which is a derivative of amino acid cysteine, metabolized into glutathione prevents alcoholic liver damage and also supports body's immune system and colon health.

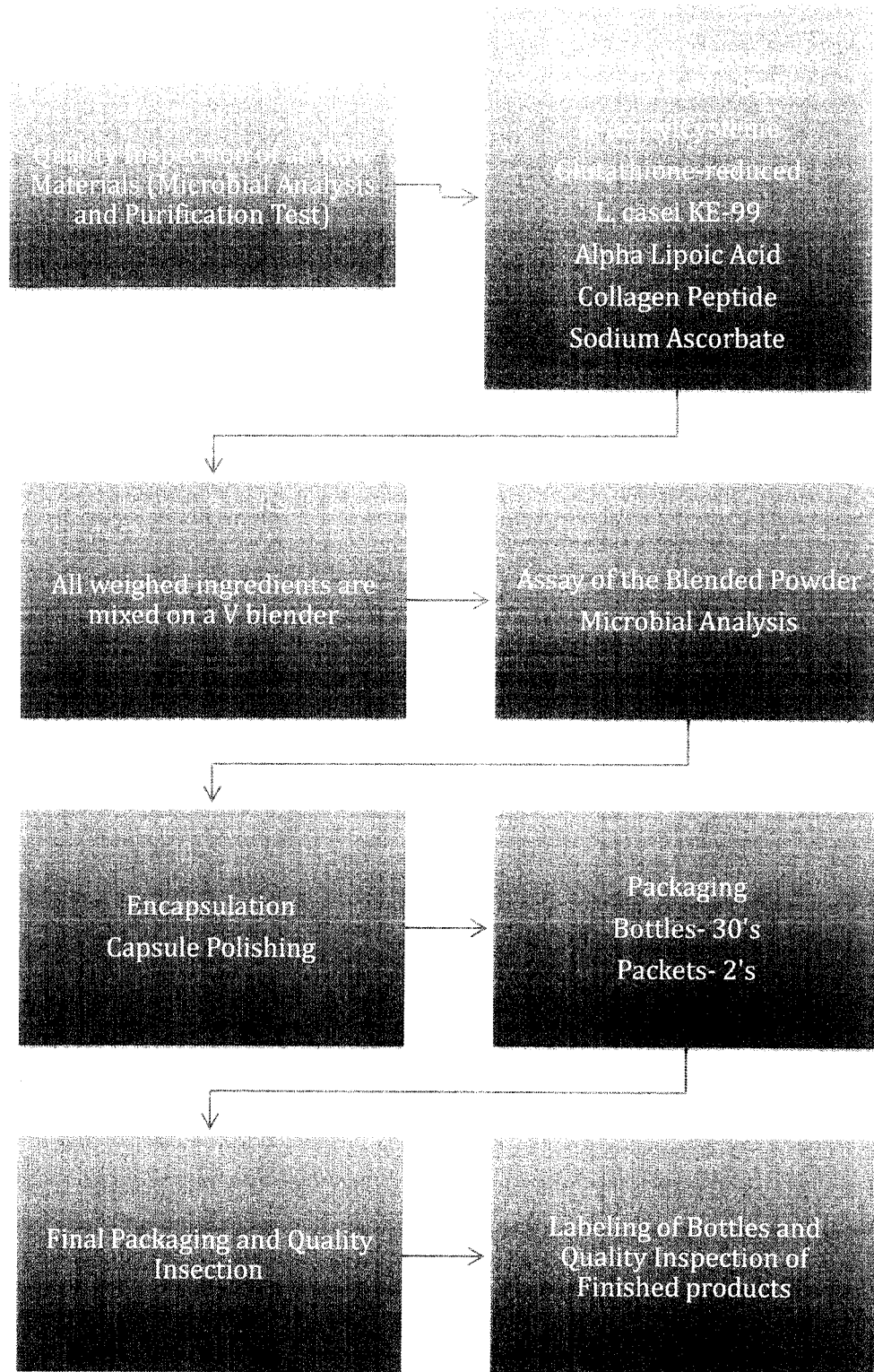
8 The composition of claim 5 wherein Alpha Lipoic Acid has a distinct characteristic for it is water and fat soluble, blocks free radicals and helps replenish intracellular GSH both in aqueous and non-aqueous system in the body.

9 The composition of claim 5 wherein Vitamin C is in the form of Sodium Ascorbate, more bioavailable form of Vitamin C which is essential to synthesize collagen and boosts the immune response.

/v The composition of claim 1 wherein the composition is in the form of preparation consisting of capsule, tablet, cream, emulsion, lotion, ointment and foam.

// The composition of claim 1 combined in one is safe and has the potential to provide essential benefit.

BRIEF DESCRIPTION OF DRAWINGS



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