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SKIN CARE COMPOSITION

The present invention relates to a dermatological composition and, more particularly, to a skin care composition having as its ingredients the combination of Phytoplenolin, dipotassium glycyrrhezinate, glycolic acid and salicylic acid, as a useful agent for skin cell renewal, reduction of comedones soothing action, skin smoothening and skin pore refinement.

Phytoplenolin is a natural botanical ingredient that helps gently exfoliate the skin as it helps heal and soothe irritated or otherwise damaged skin through a potent anti-inflammatory activity. It also possesses distinct although minimal sun screen activity.

Phytoplenolin is a trade name for centipeda cunninghami by bio-Botanical, belongs to the Daisy Family (Asterace, compositae), and has aromatic perennial herbs that grow to about 30 cm high, with significantly wooly young shoots. Moreover, it is native to Australia where aborigines have used it for burns, wounds, skin infections, diarrhea and rheumatism. In traditional Chinese medicines, the plant has been used to treat colds, nasal allergies, asthma, malaria and amoebiasis. Due to its important systemic effect, it was also deemed interesting to explore the effectiveness of the plant when applied topically.

The plant centipeda cunninghami was subjected to extraction and the active ingredient is a sesquiterpene lactone. Phytoplenolin containing 0.2% sesquiterpene lactone was tested for topical anti-inflammatory properties compared with 1.0% Hyaluronic acid and no significant difference in effect was observed.

The same extract was tested for cell renewal activity compared to 2.0% alpha hydroxy acid (a very good cell renewal agent). Phytoplenolin gave a 50% reduction in stain after eleven (11) days while AHA gave 38% over the same period of time. In view of this, phytopenolin is found to be a very effective cell renewal agent

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at lower concentration without the drastic, mechanical, exfoliating and caustic effect of AHA.

The efficacy of phytoplenolin as a sun screen agent was also tested. Due to its potent anti-inflammatory properties, it also helps to protect against sunburn.

Dipotassium glycyrrhezinate is known as a potent anti-inflammatory agent. Glycyrrhetenic acid, a sapogenin derived from licorice root, is said to possess unusual antiphlogistic and anti-inflammatory properties. The equivocal result reported following the introduction of glycyrrhetenic acid into dermatological practice was due apparently to the presence of impurities or high proportion of inactive isomers. Clinical studies have shown the compound to be highly effective in the treatment of sub acute and chronic eczema's and pruritic condition. Several new organic derivatives of glycyrrhetenic acid currently available are more soluble in body fluids and are therefore more effective locally.

Glycolic acid works at the middle layer of the skin, continuing the renewal process. It brings newly created cells and increases blood supply to the surface, replenishing a rosy complexion.

Beta hydroxy acid, in the form of Salicylic acid, has been used for many years for treating acne. It penetrates the lower dermal layers, but does not cause harm to underlying tissue and other internal body organs. It has the unique property of penetrating through pores to eliminate acne-causing bacteria and helps restore the irritated skin surrounding the pore.

It has been found through clinical study that a combination of Phytoplenolin + Dipotassium glycyrrhezinate, Salicylic acid and Glycolic acid is effective in providing skin cell renewal, soothing action and smoothening of the skin.

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A principal object of the present invention is to provide a cell renewing, soothing and smoothing of the skin composition formulated from a combination of four active ingredients. The combination of Phytopenolin, Dipotassium glycyrrhezinate, Salicylic acid and Glycolic acid in suitable amounts results in a formulation in accordance with the present invention.

Another object of the present invention is to provide a skin care composition in a solution of an alcoholic base, such as ethyl alcohol, with a clear and/or slightly brownish color, which is used to promote skin cell renewal, soothing action, smoothening and skin pore refinement.

In addition, another object of the present invention is to provide a skin care composition which is of lower cost and is comparable, or is an improvement over other known skin care formulations.

Other objects, advantages and embodiments of the present invention will now be described, by way of example, with reference to the accompanying drawings wherein:

FIGURE 1 is a flow chart illustrating a preferred process for manufacturing of Phytopenolin;

FIGURE 2 is a flow chart illustrating a preferred process for manufacturing glycolic acid;

FIGURE 3 is a flow chart illustrating a preferred process for manufacturing dipotassium glycyrrhezinate; and

FIGURE 4 is a flow chart illustrating a preferred process for manufacturing salicylic acid.

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In accordance with the present invention, a skin care formulation comprised of the stated four active ingredients combined in suitable amounts produces a useful composition for skin cell renewal, reduction of comedones, soothing action, smoothening and skin pore refinement. The skin care composition according to the present invention is a combination of the active ingredients Phytopenolin; Glycolic acid; Dipotassium glycyrrhezinate; and Salicylic acid preferably in an alcoholic base solution.

Moreover, in a preferred embodiment, the skin care composition according to the present invention is prepared according to the following preferred proportions:

Raw Materials	% Weight
Phytopenolin	0.010 - 1.00%
Dipotassium Glycyrrhezinate	0.300 - 1.00 %
Ethyl Alcohol	30.00 - 50.00 %
Salicylic Acid	0.100 - 2.00%
Glycolic Acid	0.100 - 3.00 %
Demineralized Water	q.s. to 100 %

Advantageously, the skin care formulation according to the present invention, comprises Phytopenolin, Dipotassium Glycyrrhezinate, Salicylic Acid and Glycolic Acid in a solution of an alcoholic base, preferably ethyl alcohol. Moreover, the preferred quantitative ranges of active ingredients that embody a skin care formulation according to the present invention comprise 0.010-1.00% of Phytopenolin, 0.300 - 1.00 % of Dipotassium Glycyrrhezinate, 0.100 - 2.00% of Salicylic Acid, 0.100 - 3.00% of Glycolic Acid, 30.00- 50.00% of preferably ethyl alcohol, and a suitable quantity of demineralized water to yield a combined total of 100% by weight.

Accordingly, for example, in an embodiment of the present skin care formulation, the active ingredients may be combined in the following amounts: 1% of Phytoplenolin, 1% of Dipotassium Glycyrrhezinate, 2% of Salicylic Acid, 3% of Glycolic Acid, 50% of ethyl alcohol, and 43% of demineralized water to yield a combined total of 100% by weight. The skin care formulation according to the above described methodology provides a skin care composition that is a useful cell renewal composition, can reduce comedones, has a soothing action on the treated skin, and effects a smoothing and skin pore refinement to the treated skin.

In addition, the skin care formulation of the present invention is advantageously carefully adjusted to have a pH between 3.50 - 4.00 such that it is not irritating to the skin and has a specific gravity between 0.906 - 0.950.

The composition is prepared according to the following preferred manufacturing procedure:

1. Load the required Demineralized Water into a batch-mixing tank.
2. Add Phytoplenolin, mix for 10 minutes.
3. Then add Dipotassium Glycyrrhezinate, mix for 10 minutes.
4. In a separate container load, Ethyl Alcohol.
5. Add Salicylic Acid and Glycolic Acid, mix for 10 minutes until completely dissolved.
6. Then add Alcohol solution into Demineralized Water mixing tank. Mix for 20 minutes until a clear solution is obtained.

Subsequent to the preparation of the present skin formulation, the alcoholic base composition may be packaged in plastic bottles of 30 ml, 60 ml and 120 ml capacities.

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When using the skin formulation of the present invention, the face should be washed thoroughly first with soap and water, then dried using a clean towel. Subsequently, small amounts of the solution are dabbed onto a piece of cotton and then applied evenly onto the desired facial area.

The efficacy and safety of the present skin care composition has been described by way of an extensive clinical study.

A clinical study entitled "A double blind clinical test of alcoholic base solution containing Phytoplenolin, Dipotassium Glycyrrhezinate, Salicylic Acid and Glycolic Acid versus alcoholic base solution containing Tretinoin plus Melawhite (0.025% & 2.0% respectively)" has been effected to demonstrate the efficacy and safety of the skin care formulation according to the present invention. The present clinical study will now be described with respect to the study criteria, materials used, preferred method of use of the present composition, and the resultant efficacy and safety of the present composition.

The presently described clinical study was conducted by Dr. Nenita L. Alberto and was funded by Splash Manufacturing Corporation.

One of the main goals of facial skin care is the maintenance of a fair and smooth complexion that basically fits well into our modern-day concept of beautiful skin. However, the effects of factors like atmospheric dirt, smoke and UV radiation, coupled with the intrinsic factors of genetics and aging, would require more than basic cleansing. We need to deal with skin problems like pimples, comedones, and various skin eruptions and pigment disorders.

The optimum combination of the following substances was designed in an alcoholic base formulation to counter various facial skin disorders and promote a fairer, smoother skin complexion. Accordingly, a combination of the active ingredients

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Phytoplenolin, Dipotassium, Glycyrrhezinate, Salicylic Acid and Glycolic Acid in suitable amounts embodies a formulation in accordance with the present invention.

The desired action on facial skin of the designed formulation can be compared to the effects achieved with the use of a Tretinoin plus Melawhite solution. Tretinoin has been known for years as an effective agent for the treatment of acne, comedones and pimples, whereby, Tretonoin principally acts by promoting visible skin cell renewal. Moreover, it is known in the prior art that the combination of Tretinoin with Melawhite results in a whitening formula used in the management of various skin pigment disorders, a synergistic activity in acne control and depigmentation activity has also been established. Consequently, the result attained by using the solution of Phytoplenolin, Dipotassium Glycyrrhezinate, Salicylic and Glycolic Acid was evaluated with respect to a Tretinoin plus Melawhite standard solution.

A principal objective of the present clinical study was to establish the safety and compare the efficacy (measured in terms of skin cell renewal, reduction of comedones, soothing action, smoothening properties and skin pore refinement) of the test solution (alcoholic solution of Phytoplenolin, Dipotassium Glycyrrhezine, Salicylic and Glycolic Acid) with that of a standard solution (alcoholic solution of Tretinoin and Melawhite).

Subjects to be included in the present clinical study, or excluded from the present clinical study, were selected based on the following criteria:

Inclusion Criteria:

1. healthy Filipinos (males/females)
2. Ages 25 to 60 years
3. Preferably with slight, moderate, to severe pimples

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Exclusion Criteria:

1. History of allergy to bleaching agents
2. History of photosensitivity reaction
3. History of usage of photo-toxic drugs, soaps, & lotions
4. Occupation requiring regular sun exposure
5. Debilitated or immuno-compromised patients
6. Pregnant or lactating women.

All volunteering subjects were interviewed and physical examination of the facial skin was effected. Only those subjects that fulfilled the required criteria were included in the present clinical study.

The test materials of the present study comprised thirty five (35) bottles, each of alcoholic solution containing Phytopienolin, Dipotassium Glycyrrhezinate, Salicylic Acid and Glycolic Acid, and a standard solution of Tretinoin plus Melawhite was also prepared and the solutions were labelled as Facial Solution Right and Facial Solution Left respectively.

The skin condition of each of the thirty five (35) subjects was evaluated at the beginning of the study based on the parameters enumerated below. Each subject was given two bottles of sample, coded Facial Solution Right and Facial Solution Left They were asked to wash their face with soap and water prior to the use of the product. Subsequently, the application of the product was done by wetting a piece of cotton ball with the solution and applying the solution evenly onto the face area every morning. The subjects used the product for three (3) weeks. After which, the efficacy and safety of the product was evaluated after the 1st, 2nd and 3rd week, employing the following evaluation criteria.

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The efficacy of the skin care formulation according to the embodiment of the present invention was based on the following:

RATING	EFFICACY PARAMETERS			
	COMEDONES	SMOOTHNESS	SKIN COLOUR	SKIN PORE REFINEMENT
0	none	very smooth	very light brown	very fine
1	mild	slightly smooth	light brown	slightly fine
2	moderate	moderate smooth	moderate brown	moderately fine
3	severe	not smooth	dark brown	not fine

Moreover, the safety of the skin care formulations being tested were based on the following:

RATING	CONDITION / SAFETY PARAMETER		
	ERYTHEMA	PRURITUS	PAPULES
0	none	none	none
1	mild	mild	mild
2	moderate	moderate	moderate
3	severe	severe	severe

It should be noted that during the present clinical study, ten (10) subjects were dismissed due to non-compliance with the presented guidelines.

The results and findings of the present clinical study will now be described with respect to the following observations and conclusions.

Comedones

More specifically, there were visible reductions in comedones, and in some cases, complete removal of comedones, was observed on the 3rd week of product usage for both sample testing products Facial Solution Right and Facial Solution Left.

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Smoothness

With respect to the smoothness of the skin, there was marked improvements observed in the skin texture after three (3) weeks of product usage for both Facial Solution Left and Facial Solution Right.

Skin colour

In addition, with respect to skin colour, lightening of skin colour was observed after three (3) weeks of product usage for both sample products Facial Solution Right and Facial Solution Left.

Refinement of Skin Pores

Moreover, the refinement of skin pores was also noted for both sample products Facial Solution Left and Facial Solution Right after three (3) weeks of product usage.

It should be noted that in the present clinical study, only one subject noted stinging with the use of Tretinoin plus Melawhite solution. However, no other cases of irritation or adverse reaction were reported.

Therefore, based on the results of the present clinical study conducted, a skin care formulation comprising the combination of Phytoplenolin, Dipotassium Glycyrrhezinate, Salicylic Acid and Glycolic Acid was found to be safe and effective among Filipinos for the improvement of skin texture, the removal of comedones, improved skin colour and refinement of skin pores. It may be inferred by one skilled in the art that a skin care formulation according to the present invention may be used by various individuals for a marked improvement in the appearance of skin.

While preferred embodiments have been shown and described, it will be understood that there is no intent to limit the invention to such disclosure, but rather it is intended to cover all modifications and alternate applications falling within the spirit and scope of the present invention.

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THE EMBODIMENTS FO THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINES AS FOLLOWS:

1. A dermatological composition comprising as active ingredients Phytoplenolin, Dipotassium Glycyrrhezinate, Glycolic Acid and Salicylic Acid.

2. A dermatological composition according to claim 1, wherein said active ingredients comprise Phytopenolin, Dipotassium Glycyrrhezinate, Salicylic Acid and Glycolic Acid combined in a solution of an alcoholic base.

3. A dermatological composition according to claim 2, wherein the alcoholic base is ethyl alcohol.

4. A dermatological composition according to claim 1, 2 or 3, which provides skin cell renewal, reduction of comedones, improvement of skin colour, soothing action, skin smoothening and skin pore refinement and which comprises by weight from 0.010-1.00% of Phytoplenolin, 0.300 - 1.00 % of Dipotassium Glycyrrhezinate, 0.100 - 2.00% of Salicylic Acid, 0.100 - 3.00% of Glycolic Acid, 30.00- 50.00% of an alcoholic base, and a suitable quantity of demineralized water to yield a combined total of 100% by weight.

5. A dermatological composition according to claim 1, wherein the Phytoplenolin is obtained by extraction from the plant centipeda cunninghami, to yield Phytopenolin containing sesquiterpene lactones, wherein said active compound containing sesquiterpene lactones effects topical anti-inflammatory properties.

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6. A method of producing a dermatological composition according to any one of claims 1 to 5, which comprises:

(a) loading demineralized water into a batch-mixing tank;
(b) adding Phytoplenolin, and mixing for 10 approximately minutes;
(c) subsequently adding Dipotassium Glycyrrhezinate, and mixing for approximately 10 minutes;
(d) loading ethyl alcohol into a separate container;
(e) adding Salicylic Acid and Glycolic Acid to the ethyl alcohol and mixing for approximately 10 minutes or until completely dissolved; and
(f) adding said alcoholic base solution into the demineralized water mixing tank and mixing for approximately 20 minutes until the solution is clear.

7. A method according to claim 6, wherein, the pH of the skin care formulation is adjusted to 3.50 to 4.00.

8. A method according to claim 6 or 7, wherein, the specific gravity of the skin care formulation is adjusted between 0.906 to 0.950.

9. A method according to claim 6, 7 or 8, wherein subsequent to production, the skin care formulation is packaged into bottles to facilitate its dermatological use.

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10. A method of using a dermatological composition according to any one of claims 1 to 5, comprising:

(a) washing the face or skin to be treated thoroughly with soap and water;

(b) drying the face or skin;

(c) dabbing the dermatological composition onto a piece of cotton; and

(d) subsequently applying the composition evenly onto the face or skin to be treated at least once a day.

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FIGURE 1