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SKIN CARE COMPOSITION

The present invention relates to a skin care composition and, more particularly, to a liquid skin care composition which provides good skin cell renewal, reduction of comedones, improvement of skin colour, soothing action, skin smoothening and skin pore refinement.

The present invention relates to a skin care composition, and more specifically to a liquid skin care composition of the type which is in general use for the treatment of many facial skin disorders. Such compositions are particularly suitable for skin cell renewal, reduction of comedones, improvement of skin colour, soothing action, skin smoothening and skin pore refinement.

It is known in the relevant prior art, that there are several skin care formulations presently commercially available. Generally, these formulations are of liquid composition which include a large proportion of one or more dermatological agents which are recognized as providing dermatological action, and which also provide good skin care complexion.

For example, dermatological agents include Tretinoin and Hydroquinone have been used as therapeutic agents for acne and pigmentary disorders for several years.

Stuttger first suggested topical Tretinoin (Vitamin A acid, Retinoic Acid) for topical use in 1962. The usefulness of Tretinoin has been firmly established as a compound for the treatment of various skins disorders, particularly those associated with hyperkeratosis, parakeratosis and follicular plugging.

Following topical Tretinoin application it is metabolite of retinol, which acts by alteration of follicular keratinization, it also enhances collagen synthesis in tissue and increases the destiny of anchoring fibrils along the cutaneous membrane

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zone in adult human skin. Its use in higher concentration is associated with the development of mild irritation and erythema and sensitivity to sunlight.

Hydroquinone acts by the destruction of melanosome formation and by the alteration of melanosome structure resulting in a bleaching effect on the skin. For several years it had been established as an effective whitening ingredient. It has been found in several clinical studies that Tretinoin plus Hydroquinone is effective in the treatment of acne and pigmentary disorders.

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 conditions. Several new organic derivatives of glycyrrhetenic acid currently available are more soluble in body fluids and are therefore more effective locally.

While several known dermatological formulations provide useful skin care compositions, there remains a continuing need in the present art for improvements to skin care compositions, and more particularly to the provision of an efficacious skin care composition.

An optimum combination of the following substances was prepared in an alcoholic base formulation to counter various facial skin disorders and promote the appearance of a fairer, smoother skin complexion.

The desired action or effects of the present dermatological formulation on facial skin can be compared to the effects achieved with the use of a Tretinoin plus

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Hydroquinone solution. As such, the results attained by using a skin care formulation comprised of Tretinoin, Hydroquinone and Dipotassium Glycyrrhezinate were evaluated with reference to a standard solution of Tretinoin plus Hydroquinone.

A principal object of the present invention is to provide a dermatological formulation for skin cell renewal, reduction of comedones, reduction of pigmentary disorders, soothing and smoothing of the skin, and skin pore refinement.

The skin care composition according to present invention is formulated from a combination of three active ingredients. Thus, the combination of active ingredients Tretinoin, Hydroquinone and Dipotassium Glycyrrhezinate in suitable amounts results in a dermatological formulation according to the present invention.

Another object of the invention is to provide a skin care composition in a solution of an alcoholic base, such as ethyl alcohol, with a clear colour. A greenish yellow solution upon exposure become brown in colour, which is used to promote skin cell renewal, reduction of comedones, pigmentary disorders, soothing action and smoothing of the skin and skin pore refinement.

In accordance with the present invention, a skin care formulation comprised of a combination of active ingredients Tretinoin, Hydroquinone and Dipotassium Glycyrrhezinate in suitable amounts produces a useful skin care composition for skin cell renewal, reduction of comedones, reduction of pigmentary disorders, soothing and smoothing of the skin, and skin pore refinement. Moreover, in accordance with a preferred embodiment of the present invention, the stated three active ingredients are combined in an alcoholic base solution, wherein ethyl alcohol is a preferred alcoholic base solution.

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The present invention provides a skin care composition for skin cell renewal, reduction of comedones, improvement of skin colour, soothing action, skin smoothening, and skin care pore refinement which is comprised essentially in parts by weight of the following preferred constituents:

Ingredients	% Weight
Ethyl Alcohol	35.00 - 55.00 %
Tretinoin	0.005 - 0.05 %
Hydroquinone	0.500 - 4.00 %
Dipotassium Glycyrrhezinate	0.100 - 1.00 %
EDTA	0.010 - 0.05 %
Demineralized Water	q.s. to 100 %

Advantageously, the skin care formulation according to the present invention comprises Tretinoin, Hydroquinone and Dipotassium Glycyrrhezinate 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 35.00-55.00% Ethyl Alcohol, 0.005-0.05% Tretinoin, 0.500-4.00% Hydroquinone, 0.100-1.00% Dipotassium Glycyrrhezinate, 0.010-0.05% EDTA, 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: 55% Ethyl Alcohol, 0.05% Tretinoin, 4.00% Hydroquinone, 1.00% Dipotassium Glycyrrhezinate, 0.05% EDTA, and 39.9% of demineralized water to yield a combined total of 100% by weight. The skin care composition according to the above embodiment provides a skin care composition that is useful for skin cell renewal, reduction of comedones, improvement of skin colour, soothing action, skin smoothening, and skin care pore refinement.

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In addition, the skin care formulation of the present invention is advantageously carefully adjusted to have a pH between 3.50 - 5.00 such that it is not irritating to the skin and has a specific gravity between 0.900 - 0.950.

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

1. Load the required Ethyl Alcohol into a batch mixing tank.
2. Add Tretinoin, mix for 10 minutes.
3. Then add Hydroquinone and mix for 10 minutes.
4. In a separate mixing tank, load Demineralized Water.
5. Then add Dipotassium Glycyrrhezinate; mix for 10 minutes or until completely dissolved.
6. Then add EDTA with mixing for 5 minutes.
7. 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 care formulation, the alcoholic base composition may be packaged in plastic bottles of 30 ml, 60 ml and 120 ml capacities.

When using the skin formulation of the present intention, 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 applied evenly onto the desired facial area.

A clinical study was conducted to determine the efficacy and safety of a skin care composition containing the said active ingredients in their preferred corresponding ranges in an alcoholic solution. The efficacy and safety of the present

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skin care composition has been described by way of the following extensive clinical study.

A clinical study entitled "A double blind clinical test of alcoholic base solution containing 0.025 % Tretinoin, 2.0 % Hydroquinone, with 1.0 % Dipotassium Glycchereznate versus Alcoholic Base Solution containing Tretinoin plus Hydroquinone (0.025% & 2.0% respectively) in the cell renewal, reduction of comedones, pigmentary disorders, soothing and smoothening and refine of skin pores" 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 subject selection, materials used, preferred method of use, 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.

Skin care products are formulated to not only be safe to consumers, but skin care compositions are also formulated so that they will deliver product efficacy. Thereby, keeping skin clean and free of blemishes, which is one of the main problems of adolescence.

The following ingredients were combined and formulated in a hydroalcoholic solution, namely Tretinoin, Hydroquinone and Dipotassium Glyccherizinate.

Tretinoin has been known for years as an effective agent for the treatment of acne, comedones and pimples. It principally acts by promoting visible skin cell renewal. The combination of Tretinoin with Hydroquinone, 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

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established. Dipotassium Glyccherizenate is also known as an anti-inflammatory agent.

A principal object of the present clinical study was to establish the safety and compare the efficacy (measured in terms of skin cell renewal, reduction of comedones, pigmentary disorders, soothing action, smoothening properties and skin pore refinement) of the test solution, (alcoholic solution of Tretinoin, Hydroquinone and Dipotassium Glycyrrhezinate) with that of a standard solution (alcoholic solution of Tretinoin and Hydroquinone).

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

Inclusion Criteria:

1. Healthy Filipinos (males/females)
2. Ages 20 to 60 years
3. Preferably with slight, moderate, to severe pimples
4. Dark skinned (morena or type IV)

Exclusion Criteria:

1. History of allergy to bleaching agents
2. History of photosensitivity reaction
3. History of usage of phototoxic 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 study.

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

The skin condition of each of the thirty five (35) respondents was evaluated at the beginning of the study based on the parameters enumerated below. Each subject was given two bottles of sample, coded Right Facial Solution and Left Facial Solution. 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 once a day before bedtime. The subjects used the product for three weeks. After which, the efficacy and safety of the product was evaluated after the 1st, 2nd and 3rd week, employing the following evaluation criteria:

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

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

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

RATING	CONDITION / SAFETY PARAMETER		
	ERYTHEMA / BURNING SENSATION	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 there were no dropouts, that is to say no 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 the product usage on all subjects for both sample testing products Facial Solution Left and Facial Solution Right.

Skin Colour

With respect to skin colour, the best range of efficacy of a whitening solution is the lightening of the skin colour which was observed on day 14 and increased lightening of the skin on day 21 for both sample testing products Facial Solution Left and Facial Solution Right.

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Smoothness

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

Stinging

On the seventh day, 4 out of 35 subjects experienced mild stinging with the Right Facial Solution, while 17 of the subjects experienced mild to moderate stinging with the Left Facial Solution, in which 4 respondents experienced mild stinging up to 14 days of product application.

Refinement of Skin Pores

In addition, the visible refinement of skin pores was noted for Right Facial Solution while slight skin pore refinement was observed for Left Facial Solution after three weeks of product usage.

It should be noted that in the present clinical study, none of the subjects complained of irritation, pruritus, papules or burning sensation.

Therefore, based on the results of the clinical study conducted, the combination of Tretinoin, Hydroquinone and Dipotassium Glycyrrhezinate, was found to be safe and effective for use among Filipinos in skin cell renewal, reduction of comedones, improvement of skin color, improvement of skin texture, 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 Tretinoin, Hydroquinone and Dipotassium Glycyrrhezinate.

2. A dermatological composition according to claim 1, wherein said active ingredients comprise Tretinoin, Hydroquinone and Dipotassium Glycyrrhezinate 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 0.005 0.05% Tretinoin, 0.500 4.00% Hydroquinone, 0.100-1.00% Dipotassium Glycyrrhezinate, 35.00-55.00% of an alcoholic base, 0.010-0.05% EDTA, and a suitable quantity of demineralized water to yield a combined total of 100% by weight.



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5. A method of producing a dermatological composition according to any one of claims 1 to 4, which comprises:

(a) loading an alcoholic base into a batch mixing tank;
(b) adding Tretinoin, and mixing for about 10 minutes;
(c) subsequently adding Hydroquinone and mixing for approximately 10 minutes;
(d) loading Demineralized Water into a separate mixing tank;
(e) adding Dipotassium Glycyrrhezinate thereto and mixing for approximately 10 minutes or until completely dissolved;
(f) then adding EDTA with mixing for 5 minutes; and
(g) subsequently adding the alcohol base solution into the Demineralized Water mixing tank and mixing for approximately 20 minutes until a clear solution is obtained.

6. A method according to claim 5, wherein, the pH of the skin care formulation is adjusted to 3.50 to 4.00.

7. A method according to claim 5 or 6, wherein, the specific gravity of the skin care formulation is adjusted to between 0.906 to 0.950.

8. A method according to claim 5, 6 or 7, wherein subsequent to production, the skin care formulation is packaged into bottles to facilitate its dermatological use.

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9. A method of using a dermatological composition according to any one of claims 1 to 4, comprising:

(a) washing the face or skin of a subject 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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