

US 20060134147A1

### (19) United States

# (12) Patent Application Publication (10) Pub. No.: US 2006/0134147 A1 Kalafsky (43) Pub. Date: Jun. 22, 2006

(54) COSMETIC COMPOSITIONS HAVING CARNITINE CREATINATE AND METHODS FOR USING

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(21) Appl. No.: 11/018,901

(22) Filed: Dec. 21, 2004

#### **Publication Classification**

(51) Int. Cl. A61K 31/4166 (2006.01) A61K 9/00 (2006.01)

#### (57) ABSTRACT

There is a topical composition having carnitine creatinate and a cosmetically acceptable vehicle. There is also provided a method for improving the aesthetic appearance of skin. There is also provided a method for inhibiting the induced lipid synthesis in skin. There is also provided a method for inhibiting the formation of cellulite in skin.

## COSMETIC COMPOSITIONS HAVING CARNITINE CREATINATE AND METHODS FOR USING

#### BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates to a topical composition that improves the aesthetic appearance of skin. The present invention also relates to a topical composition that inhibits induced lipid synthesis in skin. The present invention further relates to a topical composition that inhibits the formation of cellulite in skin.

[0003] 2. Description of the Related Art

[0004] Fat may build up underneath the surface of the skin due to induced lipid synthesis in the adipose layer of the skin. The buildup may take the form of a multiplicity of small but recognizable pockets of fat underneath the surface of the skin. Such buildup is commonly referred to as cellulite. Cellulite may impart an unnatural appearance to the skin. Skin can appear lumpy and discontinuous.

[0005] It would be desirable to have a topical composition that inhibited induced lipid synthesis in the skin. It would also be desirable to have a topical composition that inhibited the formation of cellulite in skin. It would further be desirable to have a topical composition that improves the aesthetic appearance of skin.

#### SUMMARY OF THE INVENTION

[0006] It is an object of the present invention to provide a topical composition that improves the aesthetic appearance of skin.

[0007] It is another object of the present invention to provide a topical composition that inhibits the induced lipid synthesis in skin.

[0008] It is still another object of the present invention to provide a topical composition that inhibits the formation of cellulite in skin.

[0009] It is yet another object of the present invention to provide a topical composition having carnitine creatinate and a cosmetically acceptable vehicle.

[0010] It is a further object of the present invention to provide a method for improving the aesthetic appearance of skin by providing a composition having a cosmetically acceptable vehicle and an effective amount of carnitine creatinate that is topically applied to the skin.

[0011] It is yet a further object of the present invention to provide a method for inhibiting induced lipid synthesis in skin by providing a composition having a cosmetically acceptable vehicle and an effective amount of carnitine creatinate that is topically applied to the skin.

[0012] It is still yet a further object of the present invention to provide also a method for inhibiting the formation of cellulite in skin by providing a composition having a cosmetically acceptable vehicle and an effective amount of carnitine creatinate that is topically applied to the skin.

### DETAILED DESCRIPTION OF THE INVENTION

[0013] The active ingredient in the composition is carnitine creatinate. Carnitine creatinate is represented by the following structure:

$$\begin{pmatrix}
+ & NH_2 \\
H_2N & N & - \\
CH_3 & O & \\
O & OH & - \\
O & & + \\
\end{pmatrix}$$
•X H<sub>2</sub>O

[0014] wherein X is an integer of 0 to about 5.

[0015] Carnitine creatinate is a salt of the acid-base reaction between carnitine and creatine. Carnitine creatinate is available commercially as a 100% active from American International Chemical, Inc. Carnitine creatinate is further described in U.S. Pat. No. 5,994,581, which is incorporated herein by reference in its entirety.

[0016] The carnitine creatinate is present in an amount effective to improve the aesthetic appearance of skin. The carnitine creatinate may also be present in an amount effective to inhibit induced lipid synthesis. The carnitine creatinate may further be present in an amount effective to inhibit formation of cellulite. Preferably, the carnitine creatinate is present at about 0.01 wt % to about 25 wt % based on the total weight of the composition. More preferably, the carnitine creatinate is present at about 0.05 wt % to about 10 wt %. Most preferably, the carnitine creatinate is present at about 0.1 wt % to about 5 wt %.

[0017] Compositions useful in the present method have a vehicle that is pharmaceutically or cosmetically acceptable. Such vehicles include, but are not limited to, one or more lower alcohols, fatty alcohols, fatty ethers, fatty esters, isododecane, polyols, glycols, liposomes, laminar lipid materials, water, or any combinations thereof.

[0018] The composition may take any product form known in the art. Useful forms include, but are not limited to, aerosol spray, cream, lotion, gel, foam, ointment, mask, mousse, patch, powder, pump spray, stick, tape, towelette, and pomade. Liquid forms of the composition may be any type, such as a solution, suspension, dispersion, or emulsion. Useful emulsion forms include oil-in-water, water-in-oil, silicone-in-water, water-in-silicone, and triple emulsions. The composition may be aqueous or anhydrous.

[0019] Compositions may also include one or more of the following optional ingredients: amino acids, anesthetics, anti-acne agents, anti-allergenics, antifungals, antimicrobials, anti-inflammatory agents, anti-irritants, antioxidants, antiseptics, antivirals, chelating agents, colorants, depigmenting agents, emollients, emulsifiers, exfoliants, for example,  $\alpha$ -hydroxy acids such as lactic acid and glycolic acid,  $\beta$ -hydroxy acids, sugar acids, oxa acids, and oxa diacids, film formers, fragrances, humectants, hyper- and hypopigmenting agents, self-tanning agents, insect repel-

lents, lubricants, moisturizers, peptides, pharmaceutical agents, photostabilizing agents, preservatives, retinoids, vitamins and vitamin derivatives such as niacin (nicotinic acid) and ascorbic acid and its derivatives, salicylic acid, skin protectants, skin penetration enhancers, staining agents, sunscreens, stabilizers, surfactants, thickeners, viscosity and/or rheology modifiers, or any combinations thereof.

[0020] The composition is also useful in preventing, ameliorating or treating acne; preventing, ameliorating or treating oily skin; preventing, ameliorating or treating oily hair; preventing, ameliorating or treating oily scalp; preventing, ameliorating or treating skin blemishes; preventing, ameliorating or treating skin breakouts; and improving skin texture.

[0021] The composition may be applied to the skin one or more times per day as needed or desired. If desired, the composition may be applied twice or more per day. Generally, the composition is applied as often as needed to impart and maintain a desirable aesthetic appearance to the skin or to maintain a skin appearance substantially free of cellulite. Typically, beneficial results are observed following daily application of the topical composition for a period of one week, preferably two weeks, especially four weeks, and most preferably after eight weeks.

[0022] In another aspect of the invention, there is a hydrogel patch that incorporates the carnitine creatinate, which is admixed with the hydrogel base. The patch can be affixed to an area of the skin of the user in need of fat reduction, for example, the inner thigh of the user. The patch is applied to the skin for a period of time effective for treatment, e.g., four or more hours per day for one day or two days, after which time the patch is removed. A second patch is then affixed, and the process is repeated over an extended period of time, i.e., about four weeks, preferably eight weeks, and most preferably 12 weeks.

[0023] In view of the foregoing, it is surprising that the aesthetic appearance of the skin can be improved by the topical application of the compositions of the present invention. It is further surprising that induced lipid synthesis in the skin can also be inhibited by the topical application of the compositions of the present invention. It is still further surprising that the formation of cellulite can be inhibited by such topical application.

[0024] The following are examples of the present invention. Unless otherwise indicated, all percentages or parts are by weight.

#### **EXAMPLES**

#### Examples 1 and 2

[0025] Compositions of the present invention in gel (Composition A) and cream (Composition B) forms are prepared. Ingredients of the compositions are set forth in Table 1 below.

TABLE 1

Ingredients	Composition A (Gel) (Wt. %)	Composition B (Cream) (Wt. %)
Carnitine creatinate Glycerin	0.1–5.0 3.0–5.0	0.1-5.0 3.0-7.0
Propylene glycol	1.0-3.0	3.0 7.0

TABLE 1-continued

Ingredients	Composition A (Gel) (Wt. %)	Composition B (Cream) (Wt. %)
Thickener	0.5-1.0	0.5-1.0
Ethanol	0.1-5.0	
Emulsifier		1.0-10.0
Oil		1.0-10.0
Ester		1.0-10.0
Wax		0.1-5.0
Silicone oil		0.1-5.0
Powder		0.0-2.0
Preservative	0.1-0.7	0.1-0.7
Water	QS 100.0%	QS 100.0%

[0026] Composition A is prepared by admixing the ingredients together at 25° C. to 30° C. and allowing the mixture to thicken to form a gel.

[0027] Composition B is made by forming an aqueous phase premix of water and water soluble components, which premix is heated to  $80^{\circ}$  C. and an oil phase premix of oil, silicone, wax, ester components, and an emulsifier, which premix is heated to  $80^{\circ}$  C. The oil phase is then blended with the water phase, and cooled to room temperature.

[0028] Compositions A and B are applied to areas of the body in need of fat reduction, in particular to the arms, thighs, and buttocks. Compositions A and B are applied daily for a period of time, typically about eight weeks, to effect an improvement in the appearance of the skin, in particular, an observable reduction in fat density, circumference and the unwanted appearance of cellulite.

#### Example 3

[0029] A hydrogel patch is prepared by premixing the carnitine creatinate and the hydrogel base. The patch is affixed to the area of the skin of the user in need of fat reduction, for example, the inner thigh of the user. The patch is removed after 1 to 2 days and a second patch is then affixed. The process is then repeated over a period of eight weeks

[0030] It should be understood that the foregoing description is only illustrative of the present invention. Various alternatives and modifications can be devised by those skilled in the art without departing from the invention. Accordingly, the present invention is intended to embrace all such alternatives, modifications and variances that fall within the scope of the appended claims.

1. A topical composition, comprising:

carnitine creatinate; and

- a cosmetically acceptable vehicle.
- 2. The composition of claim 1, wherein the carnitine creatinate is present in an amount effective to improve the aesthetic appearance of skin.
- **3**. The composition of claim 1, wherein the carnitine creatinate is present in an amount effective to inhibit induced lipid synthesis in skin.
- **4**. The composition of claim 1, wherein the carnitine creatinate is present in an amount effective to inhibit cellulite formation in skin.

- **5**. The composition of claim 1, wherein the carnitine creatinate is present at about 0.01 wt % to about 25 wt % based on the total weight of the composition.
- **6**. The composition of claim 1, wherein the carnitine creatinate is present at about 0.05 wt % to about 10 wt % based on the total weight of the composition.
- 7. The composition of claim 1, wherein the carnitine creatinate is present at about 0.1 wt % to about 5 wt % based on the total weight of the composition.
- **8**. A method for improving the aesthetic appearance of skin, comprising: topically applying to the skin a composition having a cosmetically acceptable vehicle and an effective amount of carnitine creatinate.
- 9. The method of claim 8, wherein the carnitine creatinate is present at about 0.01 wt % to about 25 wt % based on the total weight of the composition.
- 10. The method of claim 8, wherein the carnitine creatinate is present at about 0.05 wt % to about 10 wt % based on the total weight of the composition.
- 11. The method of claim 8, wherein the carnitine creatinate is present at about 0.1 wt % to about 5 wt % based on the total weight of the composition.
- 12. The method of claim 8, wherein the vehicle has an adjuvant selected from the group consisting of one or more lower alcohols, fatty alcohols, fatty ethers, fatty esters, isododecane, polyols, glycols, liposomes, laminar lipid materials, water, and any combinations thereof.
- 13. The method of claim 8, wherein the composition is in the form of a product selected from the group consisting of aerosol spray, cream, lotion, gel, foam, ointment, mask, mousse, patch, powder, pump spray, stick, tape, towelette, patch, and pomade.

- 14. The method of claim 8, further comprising one or more optional ingredients selected from the group consisting of amino acids, anesthetics, anti-acne agents, anti-allergenics, antifungals, antimicrobials, anti-inflammatory agents, anti-irritants, antioxidants, antiseptics, antivirals, chelating agents, colorants, hyperpigmenting agents, self-tanning agents, emollients, emulsifiers, exfoliants, film formers, fragrances, humectants, hypopigmenting agents, insect repellents, lubricants, moisturizers, pharmaceutical agents, peptides, vitamins and vitamin derivatives, photostabilizing agents, preservatives, retinoids, skin protectants, skin penetration enhancers, staining agents, sunscreens, stabilizers, surfactants, thickeners, viscosity and/or rheology modifiers, and any combinations thereof.
- 15. A method for inhibiting the induced lipid synthesis in skin, comprising: topically applying to the skin a composition having a cosmetically acceptable vehicle and an effective amount of carnitine creatinate.
- 16. The method of claim 15, wherein the carnitine creatinate is present at about 0.01 wt % to about 25 wt % based on the total weight of the composition.
- 17. A method for inhibiting the formation of cellulite in skin, comprising: topically applying to the skin a composition having a cosmetically acceptable vehicle and an effective amount of carnitine creatinate.
- 18. The method of claim 17, wherein the carnitine creatinate is present at about 0.01 wt % to about 25 wt % based on the total weight of the composition.

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