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(54) Titre : COMPOSITIONS ET METHODES AMELIORANT L'ASPECT DES PORES DU VISAGE

(54) Title: COMPOSITIONS AND METHODS FOR IMPROVING THE APPEARANCE OF FACIAL PORES

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Pore Area Fraction (%)

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<th>Week 6</th>
<th>Week 8</th>
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(57) Abrégé/Abstract:
A method of improving the appearance of facial pores is provided. The method includes the step of applying a composition having an effective amount of a material that regulates IL-1 and/or hyaluronic acid synthesis to an area of facial pores, wherein the composition is applied for a period of time sufficient for the material to improve the appearance of the facial pores. In some embodiments, the material that regulates IL-1 and/or hyaluronic acid synthesis is hexyldecanol. The method may also include the step of identifying facial pores on a facial skin surface.

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[A] Vehicle  [C] 5% Hexyldecanol in [A]
Title: COMPOSITIONS AND METHODS FOR IMPROVING THE APPEARANCE OF FACIAL PORES

Fig. 1

Abstract: A method of improving the appearance of facial pores is provided. The method includes the step of applying a composition having an effective amount of a material that regulates IL-1 and/or hyaluronic acid synthesis to an area of facial pores, wherein the composition is applied for a period of time sufficient for the material to improve the appearance of the facial pores. In some embodiments, the material that regulates IL-1 and/or hyaluronic acid synthesis is hexyldecanol. The method may also include the step of identifying facial pores on a facial skin surface.
COMPOSITIONS AND METHODS FOR IMPROVING
THE APPEARANCE OF FACIAL PORES

FIELD OF THE INVENTION

The present invention relates to compositions and methods for improving the appearance of facial pores.

BACKGROUND OF THE INVENTION

The epidermis, the outermost layer of the skin, comprises a cellular continuum of four layers: the stratum corneum, the granular layer, the spinous layer, and the basal layer. Each cellular layer in the epidermis represents various stages along a process in which basal epidermal keratinocytes undergo a continuous cycle of proliferation, differentiation, and apoptosis, moving upward from the basal layer to finally yield corneocytes. These corneocytes form the cornified layer known as the stratum corneum.

Basal keratinocytes reside at the lower portion of the epidermis. These mitotically active cells undergo a proliferative cycle to generate daughter cells that are physically dislocated upward into the spinous and granular layers and undergo the process of differentiation into corneocytes. On passing through the spinous and granular layers, the cells undergo morphological changes that render them flatter in structure as they lose their cellular viability, undergo alternate keratin expression profiles, and transform into cellular remnants. On average, a younger-aged epidermis turns over in about one month, shedding the older cells and replacing them with newer ones, but this process can increase to over forty days in older skin.

The stratum corneum’s corneocytes remain connected to one another via proteins and lipids, creating a protective barrier between the organism and its outside environment. This tightly regulated epidermal permeability barrier functions as a physical and selective barrier against chemical and biological insults. Important functions of this barrier include attenuation of the penetration of free radicals and prevention of penetration of harmful radiation, including UV radiation, into deeper layers. The stratum corneum also acts as a permeability barrier and functions to prevent loss of body moisture to the outside environment. Dysfunction of this barrier can lead to chronic skin conditions, diseases, and in extreme cases can even threaten the viability of the organism.

Skin aging is a multifactorial process driven by both intrinsic (chronological aging) and extrinsic (environmental) factors, including ultraviolet (UV) exposure, environmental toxins,
pollutants, and smoking. It is well known in the art that the ability of the stratum corneum to cyclically generate new layers of skin diminishes with age so that the stratum corneum turnover rate is substantially reduced in aged skin, with the cornified layer becoming gradually thinner. This results in a reduction in the functioning capacity of the barrier so that harmful stimuli penetrate the stratum corneum more easily, leading to UV-damage, for example, of the underlying dermal layers, degradation of collagen and elastin, and eventually manifests in appearance as wrinkling and skin atrophy. Further, the barrier suffers from an age-related increase in permeability to free radicals and a reduction in the amount of lipid in the intercellular matrix, decreasing barrier capacity to diffuse toxins from deeper layers. Recovery capacity of the barrier to environmental insult is also substantially reduced with age.

Over time, facial skin pore size, particularly around the nose and cheeks, may increase. While everyone, albeit to differing degrees, develops wrinkles with age, not everyone develops enlarged facial pores. As a result perhaps, cosmetic science has focused to a great extent on understanding wrinkles, creating a large body of knowledge that has been leveraged in the development of skin care products that can help prevent and/or reduce the appearance of fine lines and wrinkles.

In comparison, not as much research has focused on the enlargement of facial pores due to aging, leaving a void that has impeded the development of skin care products that are specifically designed to be effective in preventing, reducing, or otherwise improving the appearance of facial pores. While the age at which facial pores may begin to enlarge can vary widely from individual to individual, the process can begin in the 20s and pores may continue to enlarge and become more defined between in the 40s and 50s. The present inventors have surprisingly discovered that safe and effective amounts of hexyldecanol can be used to improve the appearance of facial pores. The present inventors have also surprisingly discovered that hexyldecanol may affect certain biochemical processes related to the production of hyaluronic acid and/or IL-1, which may in turn influence the appearance of facial pores. Further, the present inventors recognized the desire for topically applied cosmetic compositions and associated methods of treatment that improve the appearance of facial pores.

SUMMARY OF THE INVENTION

A method of improving the appearance of facial pores comprising the step of applying a composition comprising an effective amount of hexyldecanol to an area of facial skin having
facial pores, wherein the composition is applied for a period of time sufficient for the hexyldecanol to improve the appearance of the facial pores.

A method of improving the appearance of facial pores comprising the steps of (a) identifying a region of facial pores on a facial skin surface and (b) applying a composition comprising an effective amount of hexyldecanol to the region of facial pores on the facial skin surface, wherein the composition is applied for a period of time sufficient for hexyldecanol to improve the appearance of the facial pores.

A method of improving the appearance of facial pores comprising the step of topically applying a composition comprising an effective amount of a material that regulates IL-1, and/or HA production to a region of facial pores, wherein the composition is applied for a period of time sufficient for said material to improve the appearance of the facial pores.

A method of improving the appearance of facial pores comprising the steps of (a) identifying a region of facial pores on a facial skin surface, and (b) applying a composition comprising an effective amount of a material that regulates IL-1, and/or HA production to the region of facial pores on the facial skin surface, wherein the composition is applied for a period of time sufficient for said material to improve the appearance of the facial pores.

In response to the technical problems identified in the background, the present invention may take other forms. Further forms of the present invention will be appreciated in the detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

It is believed that the present invention will be better understood from the following description taken in conjunction with the accompanying drawings. The referenced drawings are not to be construed as limiting the scope of present invention.

Figure 1 graphically illustrates the percent reduction in pore area fraction from an in vivo test.

DETAILED DESCRIPTION OF THE INVENTION

All percentages and ratios used herein are by weight of the total composition and all measurements made are at 25°C, unless otherwise designated. All numeric ranges are inclusive of narrower ranges; delineated upper and lower range limits are interchangeable to create further ranges not explicitly delineated.
The compositions of the present invention can comprise, consist essentially of, or consist of, the essential components as well as optional ingredients described herein. As used herein, “consisting essentially of” means that the composition or component may include additional ingredients, but only if the additional ingredients do not materially alter the basic and novel characteristics of the claimed compositions or methods.

The term “apply” or “application” as used in reference to a composition, means to topically apply or spread the compositions of the present invention onto an external human skin surface such as the epidermis.

The term “dermatologically acceptable” as used herein means that the compositions or components described are suitable for use in contact with human skin tissue without undue toxicity, incompatibility, instability, allergic response, and the like.

The term “effective amount” as used herein means an amount of a compound or composition sufficient to significantly induce a positive benefit.

The term “facial pores” when used in reference to human facial skin refers generally to facial pores visible to the naked eye, although the term facial pores may also include pores that are not visible to the naked eye. A facial pore includes both the pore opening and the skin immediately adjacent to the opening that affects the visible appearance of the pore. In some instances, facial pores may have a pore area less than 2.0 mm², or 1.0 mm², or 0.1 mm², or less than 0.09 mm² or less than 0.08 mm² or less than 0.07 mm², or less than 0.05 mm² and/or a pore area greater than 0.02 mm² or 0.04 mm². Facial pores generally, but not always, have a circular or elliptical shape at the skin surface.

The term “facial skin” as used herein refers to one or more of forehead, periorbital, cheek, perioral, chin, and nose skin surfaces.

The term “improving” when used in reference to facial pores includes preventing, delaying, and/or reducing the appearance of facial pores. “Improving” also thus includes decreasing the diameter of the pore opening and/or improving the appearance of the skin immediately adjacent the pore opening so that the overall appearance of the pore is reduced; this can be evaluated through quantitative (e.g., pore area fraction) and/or qualitative means (e.g., visual inspection by the human eye).

I. Compositions

The present invention relates to various compositions and, more specifically, to compositions for topical application to the facial skin surface. The compositions may be in a wide variety of product forms that include, but are not limited to, solutions, suspensions, lotions,
creams, gels, toners, sticks, pencil, sprays, aerosols, ointments, cleansing liquid washes and solid bars, shampoos and hair conditioners, pastes, foams, powders, mousses, shaving creams, wipes, strips, patches, electrically-powered patches, wound dressing and adhesive bandages, hydrogels, film-forming products, facial and skin masks (with and without insoluble sheet), make-up such as foundations, eye liners, and eye shadows, and the like. The composition form may follow from the particular dermatologically acceptable carrier chosen, if present in the composition.

A. Hexyldecanol

Compositions of the present invention can comprise an effective amount of hexyldecanol. In particular embodiments, the composition may comprise from 1% to 10%, alternatively from 2.5% to 10%, alternatively from 2.5% to 6%, and alternatively from 4% to 6%, of hexyldecanol by weight of the total composition.

Hexyldecanol is the INCI name of the fatty alcohol also known as 2-hexyldecan-1-ol (IUPAC name), 2-hexyldecanol, or 2-Hexyl-1-decanol. The chemical formula for hexyldecanol is C_{16}H_{34}O and the CAS number is 2425-77-6. Hexyldecanol is a widely available cosmetic solvent and is commercially available from Sigma-Aldrich, Milwaukee, Wisconsin, USA.

B. Optional Components

The compositions of the present invention may contain a variety of other ingredients provided that they do not unacceptably alter the benefits of the invention. When present, compositions of the present invention may contain from about 0.0001% to about 50%; from about 0.001% to about 20%; or, alternately, from about 0.01% to about 10%, by weight of the composition, of the optional components. The amounts listed herein are only to be used as a guide, as the optimum amount of the optional components used in a composition will depend on the specific active selected since their potency does vary considerably. Hence, the amount of some optional components useful in the present invention may be outside the ranges listed herein.

The optional components, when incorporated into the composition, should be suitable for use in contact with human skin tissue without undue toxicity, incompatibility, instability, allergic response, and the like. The compositions of the present invention may include optional components such as anti-acne actives, desquamation actives, anti-cellulite agents, chelating agents, flavonoids, tanning active, non-vitamin antioxidants and radical scavengers, hair growth regulators, anti-wrinkle actives, anti-atrophy actives, minerals, phytosterols and/or plant hormones, N-acyl amino acid compounds, antimicrobial or antifungal actives, and other useful
skin care actives, which are described in further detail in U.S. application publication No. US2006/0275237A1 and US2004/0175347A1.

The Personal Care Product Council’s *International Cosmetic Ingredient Dictionary and Handbook*, Thirteenth Edition, describes a wide variety of non-limiting cosmetic and pharmaceutical ingredients commonly used in the skin care industry, which are suitable optional components for use in the compositions of the present invention. Examples of these ingredient classes include: abrasives, absorbents, aesthetic components such as fragrances, pigments, colorings/colorants, essential oils, anti-caking agents, antifoaming agents, antimicrobials, binders, biological additives, buffering agents, bulking agents, chelating agents, chemical additives, colorants, cosmetic astringents, cosmetic biocides, denaturants, drug astringents, emollients, external analgesics, film formers or materials, opacifying agents, pH adjusters, preservatives, propellants, reducing agents, sequestrants, skin cooling agents, skin protectants, thickeners viscosity modifiers, vitamins, and combinations thereof.

Several classes of optional ingredients are discussed in more detail below.

1. Skin Tone Agents

In some embodiments, it may be desirable to also include a skin tone agent in the composition in combination with the hexyldecanol. As used herein, “skin tone” refers to generalized areas and/or regionalized areas (i.e. spots, age spots) of hyperpigmentation. As used herein, “improving the skin tone” means preventing or reducing the appearance of hyperpigmented areas.

The skin tone agents can be included to further improve overall skin tone. When present, the compositions of the present invention contain up to about 50%, 40%, 30%, 20%, 10%, 5%, or 3%, by weight of the composition, of the skin tone agent. When present, the compositions of the present invention contain at least about 0.001%, 0.01%, 0.1%, 0.2%, 0.5%, or 1%, by weight of the composition, of the skin tone agent. Suitable ranges include any combination of the lower and upper limits including suitable ranges from about 0.1% to about 50%; from about 0.2% to about 20%; or from about 1% to about 10%, by weight of the composition, of the skin tone agent. The amounts listed herein are only to be used as a guide, as the optimum amount of the skin tone agent will depend on the specific active selected since their potency does vary considerably.

Suitable skin tone agents include, but are not limited to, sugar amines, vitamin B3 compounds, arbutin, deoxyarbutin, 1,3-dihydroxy-4-alkylbenzene such as hexylresorcinol, bakuchoil (4-[(1E, 3S)-3-ethyl-3,7-dimethyl – 1,6 octadienyl] phenol or monterpene phenol),
pyreneine (available from Biotech Marine, France), panicum miliiaceum seed extract, arlatone dioic acid, cinnamic acid, ferulic acid, achromaxyl, methyl nicotinamide, oil soluble licorice extract, folic acid, undecylenic acid (i.e., undecenoic acid), zinc undecylenate, thiamine (Vitamin B1) and its hydrochloride, L-tryptophan, ficus benghalensis, phlorogine (laminaria) helianthus annuus (sunflower) and vitis vinifera (grape) leaf extract, carnosine (i.e., dragosine), methyl gentisate, 1,2-hexandiol and 1,2-octandiol (i.e., combination sold as Symdiol 68 by Symrise AG, Germany), inositol, decylenoylphenylalanine (e.g., sold under the tradename Sepiwhite by Seppic, France), kojic acid, hexamidine compounds, salicylic acid, and retinoids including retinol and retinyl propionate.

In certain embodiments, the additional skin tone agent is selected from vitamin B3 compounds, sugar amines, hexamidine compounds, salicylic acid, 1,3-dihydroxy-4-alkylbenzene such as hexylresorcinol, and retinoids. As used herein, "vitamin B3 compound" means a compound having the formula:

\[
\begin{array}{c}
\text{N} \\
\text{R}
\end{array}
\]

wherein R is - CONH₂ (i.e., niacinamide), - COOH (i.e., nicotinic acid) or - CH₂OH (i.e., nicotinyl alcohol); derivatives thereof; and salts of any of the foregoing. As used herein, “sugar amine” includes isomers and tautomers of such and its salts (e.g., HCl salt) and its derivatives. Examples of sugar amines include glucosamine, N-acetyl glucosamine, mannosamine, N-acetyl mannosamine, galactosamine, N-acetyl galactosamine, their isomers (e.g., stereoisomers), and their salts (e.g., HCl salt). As used herein, "hexamidine compound" means a compound having the formula:

\[
\begin{array}{c}
\text{NH} \\
\text{C} \\
\text{O} \\
\text{H}_2\text{N} \\
\text{R}^1
\end{array} - (\text{CH}_2)_6 - \begin{array}{c}
\text{O} \\
\text{C} \\
\text{NH} \\
\text{NH}_2 \\
\text{R}^2
\end{array}
\]

wherein R¹ and R² are optional or are organic acids (e.g., sulfonic acids, etc.). In one embodiment, hexamidine compound is hexamidine disethionate.

2. Anti-Inflammatory Agents

The composition may additionally include an anti-inflammatory agent. When present, the compositions of the present invention contain up to about 20%, 10%, 5%, 3%, or 1% by
weight of the composition, of the anti-inflammatory agent. When present, the compositions of
the present invention contain at least about 0.001%, 0.01%, 0.1%, 0.2%, 0.3%, 0.5%, or 1%, by
weight of the composition, of the anti-inflammatory agent. Suitable ranges include any
combination of the lower and upper limits. Suitable anti-inflammatory agents include, but are
no limited to nonsteroidal anti-inflammatory agents (NSAIDS including but not limited to
ibuprofen, naproxen, flufenamic acid, etofenamate, aspirin, mefenamic acid, meclofenamic acid,
piroxicam and felbinac), glycyrrhizic acid (also known as glycyrrhizin, glycyrrhizinic acid, and
glycyrrhetinic acid glycoside) and salts such as dipotassium glycyrrhizate, glycyrrhetinic acid,
licorice extracts, bisabolol (e.g., alpha bisabolol), manjistha (extracted from plants in the genus
Rubia, particularly Rubia cordifolia), and guggal (extracted from plants in the genus
Commiphora, particularly Commiphora mukul), kola extract, chamomile, red clover extract, and
sea whip extract (extracts from plant in the order Gorgonacea), derivatives of any of the
foregoing, and mixtures thereof.

3. Sunscreen Actives

The compositions of the subject invention may comprise one or more sunscreen actives
(or sunscreen agents) and/or ultraviolet light absorbers. Herein, “sunscreen active” collectively
includes, sunscreen actives, sunscreen agents, and/or ultraviolet light absorbers. Sunscreen
actives include both sunscreen agents and physical sunblocks. Sunscreen actives may be organic
or inorganic. Examples of suitable sunscreen actives are disclosed in Personal Care Product
“sunscreen agents.” Particularly suitable sunscreen actives are 2-ethylhexyl-p-
methoxycinnamate (commercially available as PARSOL™ MCX), 4,4’-t-butyl
methoxydibenzoyl-methane (commercially available as PARSOL™ 1789), 2-hydroxy-4-
methoxybenzophenone, octydimethyl-p-aminobenzoic acid, digalloyltrioleate, 2,2-dihydroxy-4-
methoxybenzophenone, ethyl4-(bis(hydroxypropyl))aminobenzoate, 2-ethylhexyl-2-cyano-3,3-
diphenylacrylate, 2-ethylhexyl-salicylate, glyceryl-p-aminobenzoate, 3,3,5-tri-
methylcyclohexylsalicylate, menthol anthranilate, p-dimethyl-aminobenzoic acid or
aminobenzoate, 2-ethylhexyl-p-dimethyl-amo-benozoate, 2-phenylbenzimidazole-5-sulfonic
acid, 2-(p-dimethylaminophenyl)-5-sulfonicbenzoxazoic acid, octocrylene, zinc oxide,
benzylidene camphor and derivatives thereof, titanium dioxide, and mixtures thereof.

In one embodiment, the composition may comprise from about 1% to about 20%, and
alternatively from about 2% to about 10% by weight of the composition, of the sunscreen active,
Exact amounts will vary depending upon the chosen sunscreen active and the desired Sun Protection Factor (SPF), which is within the knowledge of one of skilled in the art.

C. Dermatologically Acceptable Carrier

The compositions of the present invention may also comprise a dermatologically acceptable carrier (which may be referred to as “carrier”) for the composition. The phrase "dermatologically acceptable carrier", as used herein, means that the carrier is suitable for topical application to the skin, has good aesthetic properties, is compatible with the actives in the composition, and will not cause any unreasonable safety or toxicity concerns. In one embodiment, the carrier is present at a level of from about 50% to about 99%, about 60% to about 98%, about 70% to about 98%, or, alternatively, from about 80% to about 95%, by weight of the composition.

The carrier can be in a wide variety of forms. Non-limiting examples include simple solutions (e.g., aqueous, organic solvent, or oil based), emulsions, and solid forms (e.g., gels, sticks, flowable solids, or amorphous materials). In certain embodiments, the dermatologically acceptable carrier is in the form of an emulsion. Emulsion may be generally classified as having a continuous aqueous phase (e.g., oil-in-water and water-in-oil-in-water) or a continuous oil phase (e.g., water-in-oil and oil-in-water-in-oil). The oil phase of the present invention may comprise silicone oils, non-silicone oils such as hydrocarbon oils, esters, ethers, and the like, and mixtures thereof.

The aqueous phase typically comprises water. However, in other embodiments, the aqueous phase may comprise components other than water, including but not limited to water-soluble moisturizing agents, conditioning agents, anti-microbials, humectants and/or other water-soluble skin care actives. In one embodiment, the non-water component of the composition comprises a humectant such as glycerin and/or other polyols. However, it should be recognized that the composition may be substantially (i.e., less than 1% water) or fully anhydrous.

A suitable carrier is selected to yield a desired product form. Furthermore, the solubility or dispersibility of the components (e.g., hexyldecanol, sunscreen active, additional components) may dictate the form and character of the carrier. In one embodiment, an oil-in-water or water-in-oil emulsion is preferred.

Emulsions may further comprise an emulsifier. The composition may comprise any suitable percentage of emulsifier to sufficiently emulsify the carrier. Suitable weight ranges include from about 0.1% to about 10% or about 0.2% to about 5% of an emulsifier, based on the weight of the composition. Emulsifiers may be nonionic, anionic or cationic. Suitable

The carrier may further comprise a thickening agent as are well known in the art to provide compositions having a suitable viscosity and rheological character.

II. Exemplary Compositions

Table 1 sets forth non-limiting examples of the compositions of the present invention.

The scope of the claims should not be limited by the preferred embodiments set forth in the examples, but should be given the broadest interpretation consistent with the description as a whole.

In the examples, all concentrations are listed as weight percent, unless otherwise specified and may exclude minor materials such as diluents, filler, and so forth. The listed formulations, therefore, comprise the listed components and any minor materials associated with such components. As is apparent to one of ordinary skill in the art, the selection of these minor materials will vary depending on the physical and chemical characteristics of the particular ingredients selected to make the present invention as described herein.

All Examples may be used to improve the appearance of one or more areas of facial pores.

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<td>Glycerin</td>
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</tbody>
</table>
The compositions of the present invention are generally prepared by conventional methods such as are known in the art of making topical compositions. Such methods typically involve mixing of the ingredients in one or more steps to a relatively uniform state, with or without heating, cooling, application of vacuum, and the like. Typically, emulsions are prepared by first mixing the aqueous phase materials separately from the fatty phase materials and then combining the two phases as appropriate to yield the desired continuous phase. The compositions are preferably prepared such as to optimize stability (physical stability, chemical stability, photostability) and/or delivery of the active materials. This optimization may include appropriate pH (e.g., less than 7), exclusion of materials that can complex with the active agent and thus negatively impact stability or delivery (e.g., exclusion of contaminating iron), use of approaches to prevent complex formation (e.g., appropriate dispersing agents or dual compartment packaging), use of appropriate photostability approaches (e.g., incorporation of sunscreen/sunblock, use of opaque packaging), etc.

III. Methods of Treatment

Various methods of treatment, application, regulation, or improvement may utilize the aforementioned compositions. In one embodiment, the method includes the step of identifying facial pores for improvement by the composition. The facial pores may be identified by the user or a third party such as a dermatologist, cosmetician, or other caregiver. Identification may be done by visual inspection of the skin for facial pores in need of treatment based on appearance. Identification may also be done by commercially available imaging devices such as the VISIA® Complexion Analysis system (available from Canfield Scientific, Inc., Fairfield, NJ). The device is capable of collecting images of the skin and identifying facial pores. In some instances, the method comprises the step of identifying a plurality of facial pores areas for treatment by the
composition. Identification of the facial pores may occur on any facial skin surface, including the forehead, perioral, chin, periorbital, nose, and/or cheek skin surfaces. In some embodiments, the facial pores of the nose and cheek skin surfaces may be targeted.

The method may comprise the step of applying the composition to facial pores, which may have been previously identified. Many regimens exist for the application of the composition to the facial pores. The composition may be applied at least once a day, twice a day, or on a more frequent daily basis, during a treatment period. When applied twice daily, the first and second applications are separated by at least 1 to about 12 hours. Typically, the composition may be applied in the morning and/or in the evening before bed.

The treatment period is ideally of sufficient time to provide an improvement in the appearance of the facial pores. The treatment period may be at least about 1 week. The treatment period may last about 4 weeks or about 8 weeks. In certain embodiments, the treatment period will extend over multiple months (i.e., 3-12 months) or multiple years. In one embodiment the composition is applied to the facial pores at least once a day during a treatment period of at least about 4 weeks or at least about 8 weeks. In one embodiment the composition is applied to the facial pores twice a day during a treatment period of at least about 4 weeks or 8 weeks.

The step of applying the composition to the facial pores may be done by localized application. In reference to application of the composition, the term “localized”, “local”, or “locally” mean that the composition is delivered to the targeted area (such as the region of facial pores) while minimizing delivery to skin surface not requiring treatment. The composition may be applied and lightly massaged into the facial pores. It is recognized that localized application does allow for a reasonable amount of the composition to be applied to areas adjacent the facial pores (i.e., the composition is unlikely to be applied or to remain within the boundary of the facial pores without some spreading). The form of the composition or the dermatologically acceptable carrier should be selected to facilitate localized application. While certain embodiments of the present invention contemplate applying a composition locally to facial pores, it will be appreciated that compositions of the present invention can be applied more generally or broadly to one or more facial skin surfaces to reduce the appearance of facial pores within those facial skin regions.

In some embodiments, the composition may be delivered by a variety of applicators appropriate for localized and general application. In another embodiment, the composition is applied to the one or more facial pores regions and more generally to one or more facial skin
surfaces contemporaneously (i.e., over a period of less than 30 minutes or, more typically, less than 5 minutes). While some methods described herein contemplate applying the compositions of the present invention with an applicator, it will be appreciated that applicators are not required and the compositions of the present invention can also be applied directly by using one’s finger or in other conventional manners.

For general application to a skin surface and, particularly a facial skin surface, the dosed amount of the composition may be between about 1 to about 50 uL/cm² per application (i.e., per single application to the skin surfaces).

One suitable method of improving the appearance of facial pores includes the step of topically applying a composition comprising an effective amount of hexyldecanol to the facial pores on a skin surface, wherein the composition is applied for a period of time sufficient for hexyldecanol to improve the appearance of the facial pores. Another suitable method of improving the appearance of facial pores includes the steps of identifying facial pores on a skin surface, applying a composition comprising an effective amount of hexyldecanol to the facial pores on the skin surface, wherein the composition is applied for a period of time sufficient for hexyldecanol to improve the appearance of the facial pores.

VI. Mechanisms of Action

Without intending to be bound by any theory, it is believed that stimulating hyaluronic acid (“HA”) production and/or regulating IL-1 may improve the appearance of facial pores. HA is known to affect the skin’s moisture level by acting as a sponge, binding up to about 1000 times its weight in water, however the enzymatic steps that constitute extracellular and intracellular HA cycles are not yet fully understood. IL-1 is associated with inflammation, which can contribute to inflammation and make facial pores appear more pronounced. Accordingly, applying an effective amount of a material that regulates HA production and/or IL-1 may also improve the appearance of facial pores. In some embodiments, hexyldecanol is used as the material for regulating HA production and/or IL-1.

According to some embodiments, the method of improving the appearance of facial pores comprises the step of topically applying a composition comprising an effective amount of a material that regulates IL-1 and/or HA production to a region of facial pores, wherein the composition is applied for a period of time sufficient for said material to improve the appearance of the facial pores.

In other embodiments, the method of improving the appearance of facial pores comprises the steps of (a) identifying a region of facial pores on a facial skin surface, and (b) applying a
composition comprising an effective amount of a material that regulates IL-1 and/or HA production to the region of facial pores on the facial skin surface, wherein the composition is applied for a period of time sufficient for said material to improve the appearance of the facial pores.

5 V. In Vivo Testing

A 9 week in vivo study was conducted using a round robin, vehicle controlled, split face design including a 1 week normalization period with 330 subjects.

Treatment Regimen – The regimen begins with a one week washout period. Each morning the subject is to wash her face with a suitable cleanser (e.g., Olay Natural Science Deep Purify Cleanser, available from The Procter & Gamble Company, Cincinnati, OH), gently dry with a towel, apply a stock moisturizer (e.g., Vehicle as described in Table 2 with 3% glycerine, no panthenol, and 0.3% disodium EDTA) to the appropriate side of the face, wait 5 minutes, and then apply a UV blocking lotion (e.g., Olay Complete All Day Moisturizing Lotion SPF 15, available from The Procter & Gamble Company, Cincinnati, OH). Each night the subject is to wash her face with a suitable cleanser (e.g., Olay Natural Science Deep Purify Cleanser, available from The Procter & Gamble Company, Cincinnati, OH), gently dry with a towel, and apply the stock moisturizer.

Each subject receives two coded test formulations for twice daily application to either the left or right side of the face. Each morning the subject is to wash her face with a suitable cleanser (e.g., Olay Natural Science Deep Purify Cleanser, available from The Procter & Gamble Company, Cincinnati, OH), gently dry with a towel, apply the test formulation to the appropriate side of the face, wait 5 minutes, and then apply a UV blocking lotion (e.g., Olay Complete All Day Moisturizing Lotion SPF 15, available from The Procter & Gamble Company, Cincinnati, OH). Each night the subject is to wash her face with a suitable cleanser (e.g., Olay Natural Science Deep Purify Cleanser, available from The Procter & Gamble Company, Cincinnati, OH), gently dry with a towel, and apply the test formulation to the appropriate side of the face. Participants are to apply 0.5g of the appropriate test formulation on each side of the face. The test formulation should be applied with the fingers using gentle pressure and in a circular motion. Test formulations included a vehicle control, and the vehicle + 5% Hexyldecanol. These test formulas are set forth in Table 2.
### Table 2

<table>
<thead>
<tr>
<th>Component</th>
<th>Vehicle</th>
<th>Vehicle + 5% Hexyldecanol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Q.S.</td>
<td>Q.S.</td>
</tr>
<tr>
<td>Hexyldecanol *A</td>
<td>---</td>
<td>5.000</td>
</tr>
<tr>
<td>Niacinamide</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Glycerin</td>
<td>7.0000</td>
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</tr>
<tr>
<td>Isohexadecane</td>
<td>3.0000</td>
<td>3.0000</td>
</tr>
<tr>
<td>Polyacrylamide(and)C13-14 Isoparaffin(and)Laureth-7 *B</td>
<td>2.0000</td>
<td>2.0000</td>
</tr>
<tr>
<td>Dimethicone and Dimethiconol *C</td>
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<td>2.0000</td>
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<tr>
<td>Isopropyl Isostearate</td>
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<tr>
<td>Tocopheryl Acetate</td>
<td>0.5000</td>
<td>0.5000</td>
</tr>
<tr>
<td>Panthenol</td>
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<td>1.0000</td>
</tr>
<tr>
<td>Cetyl Alcohol</td>
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<td>0.3200</td>
</tr>
<tr>
<td>Sucrose Polycottonseedate</td>
<td>0.6700</td>
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</tr>
<tr>
<td>Cetearyl Glucoside/Cetearyl Alcohol *D</td>
<td>0.2000</td>
<td>0.2000</td>
</tr>
<tr>
<td>Stearyl Alcohol</td>
<td>0.4800</td>
<td>0.4800</td>
</tr>
<tr>
<td>Behenyl Alcohol</td>
<td>0.4000</td>
<td>0.4000</td>
</tr>
<tr>
<td>Polymethylsilsesquioxane *E</td>
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<td>0.2500</td>
</tr>
<tr>
<td>Ethylenbaraben</td>
<td>0.2000</td>
<td>0.2000</td>
</tr>
<tr>
<td>Propylparaben</td>
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<td>0.1000</td>
</tr>
<tr>
<td>Disodium EDTA</td>
<td>0.1000</td>
<td>0.1000</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
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<td>0.2500</td>
</tr>
<tr>
<td>PEG-100 Stearate</td>
<td>0.1000</td>
<td>0.1000</td>
</tr>
</tbody>
</table>

*A – Hexyldecanol available from Sigma-Aldrich, USA or Cognis, Germany.
*B – Sepigel 305, available from SEPPIC, France.
*C – Dow Corning 1503 Fluid, available from Dow Corning, Midland, MI.

Images of the facial treatment sites are captured at baseline (week 0), and after 4 and 8 weeks of treatment and analyzed for changes to facial pores. Prior to image collection the participant’s face is washed with the above referenced cleanser and allowed to dry (approximately 20 minutes). Images are collected of the right and left side of the participant’s face. Images are collected using a digital camera (*e.g.*, Fuji F2 Pro digital SLR) equipped with a suitable lens for facial imaging (*e.g.*, 60mm Nikor lens), mounted in a standardised illumination box fitted with head-positioning. The camera was calibrated daily using a GretagMacbeth neutral 8.0 grey colour board in front of the camera. Left and right views of the face were standardised—that is, the same focal distance from the camera lens to the face, same magnification, same head position so that the camera angle was the same relative to the face surface, and exactly the same lighting. Images are saved in a suitable file format such as RAW
format at a suitable camera resolution. Lighting is provided by a flash source (e.g., 1000W strobe with color temperature of about 5600K). The camera and lighting are equipped with polarizing filters to reduce specular reflection.

The region of interest (ROI), in this case the upper cheek area, was marked manually based on 12 predefined facial landmarks around the cheek—for example, corners of the eye, bridge of the nose, corners of the mouth. The degree of facial pores in the ROI were quantified objectively using image analysis algorithms based on an Optimus software platform.

Because the ROI varies in shape and size, total pore area was normalized to total ROI size to yield a Pore Area Fraction (PAF)—that is, fractional ROI area occupied by facial pores. Group statistical analysis used the mean PAF on the left and right sides of the face for each subject. Stata 8.1 (Stata Corp, Lakeway Drive College Station, Texas, USA) was used for the statistical analysis. A multivariate logistic regression analysis obtained the maximum likelihood OR estimates and corresponding 95% CIs. Data collected from the image are used to calculate Pore Area Fraction, which is an indication of the appearance of pore area present. A lower Pore Area Fraction reflects a reduced level of the appearance of facial pores.

Hexyldecanol performed best at 8 weeks, significantly (p <= 0.10) reducing Pore Area Fraction better than the control. Figure 1 summarizes these results.

VI. Test Methods

The following methods are provided to illustrate certain features and advantages of various embodiments of the invention and should not be construed as limiting the scope thereof.

A. IL-1 inhibition assay protocol

1. Starting cells

One vial of Human ECV304 cells stably transfected with human ICAM-1 promoter/luciferase reporter construct (pGL3 basic plasmid) and CMV-βgal/RSV-neo plasmid DNA (clone E1.3-22) is placed in a 75cm flask with 15 ml of complete maintenance media defined as follows: M199 (Gibco, cat #11150-059, 1x liquid, 500ml containing Earle's salts, Na bicarbonate, and L-glutamine), 10% FBS (certified, heat-inactivated from Gibco, cat #10082-147), 10μg/ml gentamicin (Gibco, cat #15710-015 - 10mg/ml soln (1000x), and 250μg/ml geneticin antibiotic (active G418 from Gibco, cat 10131-035 - 50mg/ml soln).

2. Subculture

When cells are 85-90% confluent remove media. Dilute (10x) trypsin-EDTA (Gibco cat# 15400-039) to (1x) with HBSS and add 3ml of (1x) trypsin-EDTA to flask and rinse. Remove
trypsin and add a fresh 3ml/flask and incubate 3-4 min. Strike end of flask to detach cells, and then add 6ml of complete maintenance medium thoroughly washing the flask and place liquid in a conical tube. Then rinse each flask with an additional 3ml of maintenance media. Spin tube at 200Xg (approx 900rpm for centrifuge in 3N066H) for 7 minutes. Aspirate supernatant and resuspend cells in 10ml of maintenance media. Place 10ul of cell suspension into a hemocytometer and count cells in 5 squares. Use following equation - total\# of cells counted \times dilution \times 10^4/\# of squares counted = cells/ml. Example: 114 cells \times 10 \times 1000/5 squares = 2.3 \times 10^5 cells/ml. Use these cells to either seed 75cm flasks (at 500,000 cells/flask) or 96-well plates (see below).

3. Testing compounds

Step 1 - Seed cells into white tissue culture treated 96-well plates at 10,000 cells/well in Medium 199 supplemented with 10% heat inactivated FBS, 10ug/ml gentamicin, and 250ug/ml G418 in tissue culture treated plates (I used the PerkinElmer Viewplates-96, white, TC Cat# 6005181) for 60-65 hrs.

Step 2 - Remove media and replace with 100ul Phenol-red free Medium 199 supplemented with 10% heat inactivated FBS, 10ug/ml gentamicin, and 250ug/ml G418 +/- 10U/ml IL-1 beta, +/- test compounds.

Example: add 90ul of Media with 11.1 U/ml of IL-1 to each well and 10ul of compounds (for a final cmpd conc. of 100uM) to get final IL-1 conc. at 10U/ml. If using 100,000U/ml IL-1 stock: 11.1 U/ml = 5.55ul of IL-1\beta stock in 50ml media (This is enough treatment media for approximately 5 plates.)

Step 3 - Incubate the cells for 4 hours. At the end the compound treatment, the plates should be removed from the incubator and either frozen at -80°C for subsequent testing or set out at room temperature and allowed to adapt for about 30 minutes prior to reagent addition in step 4.

Step 4 - Thaw previously reconstituted steadylite substrate (stored at -80°C) to room temperature and mix thoroughly by inversion or make fresh substrate by reconstituting lyophilized steadylite substrate with steadylite HTS substrate buffer solution (as per kit instructions) and mix thoroughly by inversion until the substrate is completely dissolved. Make fresh reagents for every assay (alternatively freshly prepared substrate/lysis buffer can be stored at -80°C for one month). Before starting steadylite assay: If using frozen aliquots of steadylite substrate and/or frozen test media samples, you need to set it out in the morning so that it is
thawed and at room temperature by time that it is needed for the assay. Cold substrate and/or samples will adversely affect the assay results.

Step 5 - Add 100 ul of the substrate to the medium/cells. This step should be performed in a room with only the minimal level of lighting necessary for the researcher to be able to see how to perform the step safely and accurately.

Step 6 - Seal plate with TopSeal-A and wrap in foil, wait > 5 minutes (but not more than 5 hours) with gentle shaking to allow the cells to lyse and the reaction to proceed for full signal generation. Measure luminescence using a luminometer, such as Envision available from Perkin-Elmer Life Sciences, USA.

4. Results

Using generally the method described above, four replicates of the IL-1 assay were performed using a 5% concentration of hexyldecanol diluted to a 0.05% concentration. Hexyldecanol was found to reduce IL-1 stimulatory activity for the four replicates by 24%, 18%, 18% and 21%.

B. Hyaluronic Acid (HA) Synthase Expression

1. Keratinocyte Culture:

Individual experiments (referred to as batches) are generally comprised of 60 Affymetrix GeneChips® (referred to as “instances”) containing 6 vehicle control samples, 2 positive control samples and 52 individual test material samples. Duplication of test materials is performed across batches. In vitro testing is performed in 6-well plates to provide sufficient RNA for GeneChip® analysis (2-4 ug total RNA yield/well). Human telomerized keratinocytes are grown in EpiLife® media with 1X Human Keratinocyte Growth Supplement (Invitrogen) on collagen I coated cell culture flasks and plates (Becton Dickinson). Cells are seeded into 6-well plates at 20,000 cells /cm2 24 hours before chemical exposure. At t= - 24 hours cells are trypsinized from T-75 flasks and plated into 6-well plates in basal growth medium. At t=0 media is removed and replaced with the appropriate dosing solution as per the experimental design. Dosing solutions are prepared the previous day in sterile 4 ml Falcon snap cap tubes. After 6 hours of chemical exposure cells are viewed and imaged. Cells are then lysed with 350ul/well of RLT buffer containing β-mercaptoethanol (Qiagen), transferred to a 96-well plate, and stored at -20°C.

2. Transcriptional Screening – RNA analyzed with gene chips

Total RNA Isolation: Cells suspended in ~350 ul of RNEasy RLT Buffer (QIAGen, Hilden, Germany) plus beta-mercaptoethanol and 400 ul of Agencourt RNAClean paramagnetic
beads (Beckman Coulter Genomics, Danvers, MA). RNA was purified using a modification of the RNEasy procedure that has been optimized for automation on the Affymetrix (Santa Clara, CA) GCAS instrument.

GeneChip Target Synthesis and GeneChip Processing: 1 ug of purified total RNA is converted to cRNA GeneChip target using the Ambion (Austin, TX) MessageAmp II kit and protocol provided. 20 ug of cRNA target were fragmented and hybridized to Affymetrix U133plus2.0 arrays. Hybridization, washing, and scanning procedures were carried out according to the Affymetrix Expression Analysis protocol. Complete protocols for target synthesis and GeneChip processing can be found in Affymetrix, Inc., Gene Chip® Expression Analysis Technical Manual, with Specific Protocols for Use with Hybridization, Wash, and Stain Kit, P/N 702232 Revision 3, © 2005-2009 on the Affymetrix website.

GeneChip Analysis: GeneChip scans were converted to tabular data using the Affymetrix MAS5 algorithm, which is also described and found at the website for Affymetrix.

Data quality was determined using a variety of statistical measures, including t-tests, scatter biplots, and principal components analysis, depending upon the source and character of the data.

Data Analysis: Affymetrix probe sets are rank ordered according to p-values, and probes showing changes with p-values > 0.1 are excluded from the analysis as these are deemed not significant.

Results: Using generally the methods describe above, a microarray analysis of six Affymetrix GeneChips was processed for a keratinocyte cell culture dosed with a 10 micro molar concentration of hexyldecanol. The transcriptional expression level for the probe set IDs associated with the HAS-2 gene (Hyaluronic Acid Synthase-2 gene) had an average fold change of 1.336 (p-value = 0.0366).

The dimensions and values disclosed herein are not to be understood as being strictly limited to the exact numerical values recited. Instead, unless otherwise specified, each such dimension is intended to mean both the recited value and a functionally equivalent range surrounding that value. For example, a dimension disclosed as “40 mm” is intended to mean “about 40 mm.”

The citation of any document is not an admission that it is prior art with
respect to any invention disclosed or claimed herein or that it alone, or in any combination with any other reference or references, teaches, suggests or discloses any such invention. Further, to the extent that any meaning or definition of a term in this document conflicts with any meaning or definition of the same term in a document referenced, the meaning or definition assigned to that term in this document shall govern.

The scope of the claims should not be limited by the preferred embodiments set forth in the examples, but should be given the broadest interpretation consistent with the description as a whole.
CLAIMS

What is claimed is:

1. A method of improving the appearance of facial pores comprising the step of topically applying a composition comprising from 1% to 10% by weight of the total composition of hexyldecanol to a region of facial pores and a carrier, wherein the composition is applied for a period of time sufficient to improve the appearance of the facial pores.

2. A method of improving the appearance of facial pores comprising the step of topically applying a composition comprising an amount effective for improving the appearance of the facial pores of hexyldecanol that regulates interleukin-1 and/or hyaluronic acid production and a carrier to a region of facial pores, wherein the composition is applied for a period of time sufficient to improve the appearance of the facial pores.

3. The method of any one of claims 1 to 2, wherein the composition is applied to at least one facial area selected from the group consisting of a forehead, perioral, chin, periorbital, nose, cheek skin surface, and combinations thereof.

4. A method of improving the appearance of facial pores, the method comprising the steps of:
   a. identifying a region of facial pores on a facial skin surface; and
   b. applying a composition comprising from 1% to 10% by weight of the total composition of hexyldecanol and a carrier to the facial pores on the facial skin surface, wherein the composition is applied for a period of time sufficient to improve the appearance of the facial pores.

5. A method of improving the appearance of facial pores, the method comprising the steps of:
   a. identifying a region of facial pores on a facial skin surface; and
   b. applying a composition comprising an amount effective for improving the appearance of facial pores of hexyldecanol that regulates interleukin-1 and/or hyaluronic acid production and a carrier to the region of facial pores on the
facial skin surface, wherein the composition is applied for a period of time sufficient to improve the appearance of the facial pores.

6. The method of claim 4 or 5, wherein the step of identifying facial pores is performed by an imaging device.

7. The method of claim 4 to 5, wherein the step of identifying facial pores is performed visually by the human eye.

8. The method of any one of claims 1 to 7, wherein the composition has a concentration of hexyldecanol from 2.5% to 10% by weight of the composition.

9. The method of any one of claims 1 to 8, wherein the composition is applied to the facial pores at least once a day, for at least four weeks.

10. The method of any one of claims 1 to 9, wherein the composition is applied to the facial pores at least twice a day for at least four weeks.

11. The method of any one of claims 1 to 9, wherein the composition is applied to the facial pores at least once a day for at least eight weeks.

12. The method of any one of claims 1 to 11, wherein the composition is applied to the facial pores at least twice a day for at least eight weeks.

13. The method of any one of claims 1 to 12, wherein the composition further comprises a skin tone agent.

14. The method of claim 13, wherein the skin tone agent is a vitamin B3 compound, sugar amine, hexamidine compound, salicylic acid, 1,3-dihydroxy-4-alkylbenzene, retinoid, or combinations thereof.

15. The method of any one of claims 1 to 14, wherein the hexyldecanol applied to the facial pores region is applied at a level of from 1 to 50 uL/cm².
16. A use of a composition comprising from 1% to 10% by weight of the total composition of hexyldecanol to a region of facial pores and a carrier for improving the appearance of facial pores.

17. A use of a composition comprising an effective amount of hexyldecanol that regulates interleukin-1 and/or hyaluronic acid production and a carrier for improving the appearance of facial pores.

18. The use of any one of claims 16 to 17, wherein the composition is for application to at least one facial area selected from the group consisting of a forehead, perioral, chin, periorbital, nose, cheek skin surface, and combinations thereof.

19. A use of a composition comprising from 1% to 10% by weight of the total composition of hexyldecanol and a carrier for improving the appearance of facial pores, wherein the facial pores are in an identified region of facial skin surface.

20. A use of a composition comprising an effective amount of hexyldecanol that regulates interleukin-1 and/or hyaluronic acid production and a carrier for improving the appearance of facial pores, wherein the facial pores are in an identified region on a facial skin surface.

21. The use of claim 19 or 20, wherein an imaging device identifies the identified region.

22. The use of claim 19 to 20, wherein a visual inspection by human eye identifies the identified region.

23. The use of any one of claims 16 to 20, wherein the composition has a concentration of hexyldecanol from 2.5% to 10% by weight of the composition.

24. The use of any one of claims 16 to 23, wherein the composition is for application to the facial pores at least once a day, for at least four weeks.
25. The use of any one of claims 16 to 24, wherein the composition is for application to the facial pores at least twice a day for at least four weeks.

26. The use of any one of claims 16 to 24, wherein the composition is for application to the facial pores at least once a day for at least eight weeks.

27. The use of any one of claims 16 to 26, wherein the composition is for application applied to the facial pores at least twice a day for at least eight weeks.

28. The use of any one of claims 16 to 27, wherein the composition further comprises an anti-inflammatory agent.

29. The use of claim 28, wherein the anti-inflammatory agent is glycyrrhizic acid, glycyrrhizic acid salts, licorice extract, bisabolol, or combinations thereof.

30. The use of any one of claims 16 to 29, wherein the composition further comprises a skin tone agent.

31. The use of claim 30, wherein the skin tone agent is a vitamin B3 compound, sugar amine, hexamidine compound, salicylic acid, 1,3-dihydroxy-4-alkylbenzene, retinoid, or combinations thereof.

32. The use of any one of claims 16 to 31, wherein the hexyldecanol applied to the facial pores region is applied at a level of from 1 to 50 uL/cm².

33. The use of any one of claim 16 to 32, wherein the composition further comprises a sunscreen active.