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(71) Applicant (for all designated States except US): THE PROCTER & GAMBLE COMPANY [US/US]; One Procter & Gamble Plaza, Cincinnati, OH 45202 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): PUTMAN, Christopher, Dean [US/US]; 6747 San Mateo Drive, West Chester, OH 45069 (US). CETTI, Jonathan, Robert [US/US]; 7801 Birchwood Court, Mason, OH 45040 (US). WEL, Karl, Shiqing [US/US]; 4600 Cobblestone Court, Mason, OH 45040 (US). BIEHLE, Susan, Jeane [US/US]; 6303 Jamison Way, Liberty Township, OH 45044 (US). FARRIS, Richard, Duffy [US/US]; 7417 Quail Run Drive, West Chester, OH 45069 (US).

ABSHER, Sarah, Noelle [US/US]; 1208 Wareham Drive Apt.#2, Cincinnati, OH 45202 (US). MENON, Elton, Luis [BR/US]; 4075 Fox Hollow Court, Mason, OH 45040 (US).

(74) Common Representative: THE PROCTER & GAMBLE COMPANY; c/o Eileen L. Hughett, Global Patent Services, 299 East Sixth Street, Sycamore Building, 4th Floor, Cincinnati, OH 45202 (US).

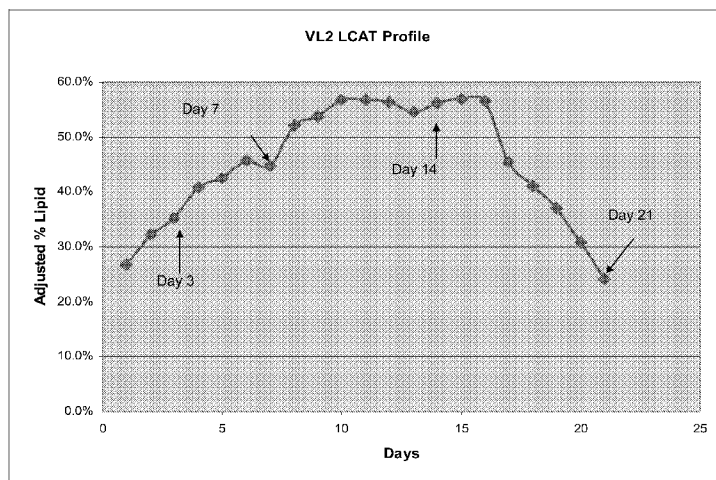
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(54) Title: METHODS FOR IMPROVING SKIN QUALITY USING RINSE-OFF PERSONAL CARE COMPOSITIONS WITH VARIABLE AMOUNTS OF HYDROPHOBIC BENEFIT AGENTS

FIG. 5



(57) Abstract: In various embodiments, provided are (i) methods and regimens for application of a personal care product for treating and maintaining the quality of skin, wherein a composition formulated to comprise at least two benefit agents, such as a lathering agent and a hydrophobic benefit agent, is applied to the user's skin over a treatment cycle that comprises two or more stages; (ii) methods for identifying and providing personal care products for treating and maintaining the quality of skin to specific populations of users; and (iii) methods for assessing, treating and maintaining the quality of skin and minimizing the signs of aging by assessing the activity of one or more skin biomarkers or physical properties that are indicative of skin quality.

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METHODS FOR IMPROVING SKIN QUALITY USING RINSE-OFF PERSONAL CARE  
COMPOSITIONS WITH VARIABLE AMOUNTS OF HYDROPHOBIC BENEFIT  
AGENTS

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation in part of U.S. Application Serial No. 12/361,494 filed January 28, 2209. This application claims priority to U.S. Applications Serial Nos. 12/361,494 filed January 28, 2209, 12/478,624 filed June 4, 2009, 61/295,732 filed January 17, 2010, and 61/295,826 filed January 18, 2010, the disclosures of which are incorporated herein by reference.

FIELD

The present disclosure relates to methods for improving skin quality by delivering personal care articles that provide a premium product usage experience for the consumer and skin benefits that persist beyond the application.

BACKGROUND

Personal care articles are well known and widely used on hair and skin for delivering actives that provide, for example, one or more benefits of cleansing, moisturizing, hiding or reducing imperfections, reducing oiliness, and providing scent to either or both the shower and the hair or skin. The efficacy of personal care compositions for cleaning and moisturizing, particularly with respect to reliving skin dryness and signs of aging, is directly related to the frequency of use and the level of benefit materials. And the pleasurable experience of using personal care compositions, particularly for the benefits of lathering and scenting, are similarly related to the frequency of use and the level of benefit materials in the personal care article.

Consumers typically have limited space to accommodate an extensive selection of personal care articles, hence they seek products that deliver the maximum benefits and pleasurable experience during use. If a treatment regime contains too many steps or too many packages, consumers often tire of the regime of personal care compositions over time. Likewise, if a personal care article contains a balance of actives that are perceived by consumers to provide an overall non-pleasurable usage experience, the consumers lose interest in using the product. As a result, in either case, consumer may decrease, suspend, or even or abandon use of the personal care article despite what may be significant benefits gained by the continued compliant use over time.

The methods as disclosed herein fulfill this need for a simplified regime that provides excellent skin benefits.

### SUMMARY

The present disclosure is directed to methods and regimens for application of a rinse-off personal care product for treating and maintaining the quality of skin and to minimize the signs of aging. Thus, in various embodiments, provided are skin treatment regimens that comprise applying to the skin of a user a composition formulated to comprise at least two benefit agents, for example a lathering agent and a hydrophobic benefit agent, wherein the composition is applied to the user's skin over a treatment cycle that comprises two or more stages. In some embodiments, the ratios of the benefit agents in the composition vary relative to one another either continuously or discretely over the treatment cycle. In some embodiments, the composition as applied during a first stage comprises a first of the varying ratios, and the composition as applied during a second stage comprises a second of the varying ratios. In some embodiments, the second ratio is lower than the first ratio. In some embodiments, the treatment cycle comprises a third stage, and the composition applied therein comprises a third of the varying ratios. In some such embodiments, the third ratio is higher than the second ratio. In some embodiments, the composition is provided to the user through a delivery article adapted to dispense the composition in discrete aliquots of approximately equal volume.

The present disclosure is also directed to methods for identifying and providing personal care products that are suitable for treating and maintaining the quality of skin. In some embodiments, the methods are directed to optimizing personal care products for specific populations of users.

The present disclosure is also directed to methods for assessing, treating and maintaining the quality of skin and minimizing the signs of aging by assessing the activity of one or more skin biomarkers that are indicative of skin quality. In some such embodiments, the methods also include assessing one or more physical properties that are indicative of skin quality.

In accordance with some embodiments, the regimens and methods as disclosed herein can be practiced using personal care articles and personal care compositions as disclosed herein.

These and other features, aspects, and advantages of the embodiments disclosed herein will become evident to those skilled in the art from a reading of the present disclosure with the appended claims.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows an exemplary profile of lathering agent to hydrophobic benefit agent.

FIG. 2 is a graph showing the lipid delivery profile according to an embodiment as described herein wherein the ratio of lathering agent to hydrophobic benefit agent varies across a treatment cycle from about 70:30 through about 45:55 to about 80:20, wherein the volume of dispensed composition is 250 ml.

FIG. 3 is a graph showing the lipid delivery profile according to an embodiment as described herein wherein the ratio of lathering agent to hydrophobic benefit agent varies across a treatment cycle from about 70:30 through about 45:55 to about 80:20, wherein the volume of dispensed composition is 450 ml.

FIG. 4 is a graph that shows representative results with two different constant lipid products (commercially available) wherein the products provide varying skin conditioning when delivered over a time period of 21 days, with measurements taken for dryness change at days 7, 14 and 21.

FIG. 5 is a chart showing the lipid delivery profile according to an embodiment as described herein wherein the ratio of lathering agent to hydrophobic benefit agent varies across a treatment cycle from about 70:30 through about 45:55 to about 80:20.

FIG. 6 is a graph showing the relative change in visual dryness using water, a personal care composition having a lathering agent to hydrophobic benefit agent ratio of 44:45 and a embodiment of personal care composition having the lipid delivery profile as shown in FIG. 5.

FIG. 7 is a graph showing the relative change in skin condition measured with a corneometer using water, a personal care composition having a lathering agent to hydrophobic benefit agent ratio of 44:45 and a embodiment of personal care composition having the lipid delivery profile as shown in FIG. 5.

FIG. 8 is a graph showing the relative change in skin trans epidermal water loss using water, a personal care composition having a lathering agent to hydrophobic benefit agent ratio

of 44:45 and a embodiment of personal care composition having the lipid delivery profile as shown in FIG. 5.

FIG. 9 is a graph showing the change in skin deformation over time.

FIG. 10 is a graph showing the relative change in Ue using water, a personal care composition having a lathering agent to hydrophobic benefit agent ratio of 44:45 and a embodiment of personal care composition having the lipid delivery profile as shown in FIG. 5.

FIG. 11 is a graph showing the relative change in Ur using water, a personal care composition having a lathering agent to hydrophobic benefit agent ratio of 44:45 and a embodiment of personal care composition having the lipid delivery profile as shown in FIG. 5.

FIG. 12 is a graph showing the relative change in total protein using water, a personal care composition having a lathering agent to hydrophobic benefit agent ratio of 44:45 and a embodiment of personal care composition having the lipid delivery profile as shown in FIG. 5.

FIG. 13 is a graph showing the relative change Keratin 1, 10 and 11 normalized to soluble protein using water, a personal care composition having a lathering agent to hydrophobic benefit agent ratio of 44:45 and a embodiment of personal care composition having the lipid delivery profile as shown in FIG. 5.

FIG. 14A and FIG. 14B illustrate a personal care article with three zones having horizontal interfaces between the compositions in each zone.

FIG. 15A is a diagram of the distinguishable layers of a personal care product after centrifugation which can be measured in length to calculate the concentration of hydrophobic benefit material in the personal care product using the Microcentrifugation Method described below.

FIG. 15B and FIG. 15C are photographs that exemplify the measurement of the length of the benefit layer used to calculate the concentration of the hydrophobic benefit material within in centrifuged samples tested using the Microcentrifugation Method described below.

FIG. 16 is a calibration curve calculated using a formula in the Microcentrifugation Method described below.

FIG. 17 illustrates a graphic user interface analysis a personal care product phase distribution along the radial dimensions of the package according to the MRI method described below.

FIG. 18 illustrates a graphic user interface analysis of a personal care product phase distribution along the height of the package according to the MRI method described below.

FIG. 19A, FIG. 19B, and FIG. 19C are MRI images of hydrophobic benefit material distribution profiles prior to and after simulated shipping conditions, as per the Dynamic Stability Shipping Method described below.

FIG. 20A, FIG. 20B and FIG. 20C are MRI images of hydrophobic benefit material distribution profiles of personal care products described in the examples below.

FIG. 21 is a chart showing the benefit phase distribution profile of the hydrophobic benefit material in the personal care products described in the examples below.

FIG. 22 is a front elevational view of a package that is separable into a plurality of sections.

FIG. 23 is a front elevation view of the package of FIG. 22, wherein the plurality of sections have been separated from each another.

FIG. 24 is a schematic illustration of a manufacturing line comprising a filling station for filling a plurality of packages simultaneously.

## DETAILED DESCRIPTION

### I. Definitions

"Ambient conditions" as used herein, refers to surrounding conditions at one (1) atmosphere of pressure, 50% relative humidity, and 25°C.

"Biomarker" as used herein refers to any biological molecules (genes, proteins, lipids, metabolites) that, singularly or collectively, reflect the current or predict future state of a biological system. Thus, as used herein, various biomarkers are indicators of the quality of skin in terms of elasticity, dryness, condition, brightness, tone, smoothness, appearance of lines. Non-limiting examples of biomarkers as indicators include, elastic properties, visual properties of dryness and condition, the presence of flaking, cohesiveness as evidenced by total protein, lipid content, trans-epidermal water loss, cytokine expression, the presence of one or more of keratins 1, 10 and 11. One or more modified biological parameters can be

used to screen for materials that induce a positive or negative effect on skin. The response of skin to treatment with personal care compositions can also be assessed by measuring one or more biomarkers.

"Consumer" as used herein refers to an individual who purchases and/or uses compositions in accordance with the disclosure. In some instances, therefore, a consumer may be alternately referred to herein as a "user."

"Comprising" as used herein is inclusive and does not exclude additional, unrecited elements, steps or methods. Terms as used herein that are synonymous with "comprising" include "including," "containing," and "characterized by," and mean that other steps and other ingredients can be included. The term "comprising" encompasses the terms "consisting of" and "consisting essentially of," wherein these latter terms are exclusive and are limited in that additional, unrecited elements, steps or methods ingredients may be excluded. The personal cleansing compositions and methods of the present disclosure can comprise, consist of, or consist essentially of, the elements, steps and methods as described herein.

"Effective amount" as used herein means an amount of a compound or composition sufficient to significantly induce a positive skin benefit, including independently or in combination with other benefits disclosed herein. This means that the content and/or concentration of active component in the formulation is sufficient that when the formulation is applied with normal frequency and in a normal amount, the formulation can result in the treatment of one or more undesired skin conditions (e.g., skin wrinkles). For instance, the amount can be an amount sufficient to inhibit or enhance some biochemical function occurring within the skin. This amount of active component may vary depending upon, among other factors, the type of product and the type of skin condition to be addressed.

"Headspace," as used herein means the void volume that is located proximal to the dispensing orifice and the interface of the first zone of the single chamber package. In the alternative, the headspace can be comprised within the first zone. The headspace of the personal care articles as disclosed herein can be determined by the following method or any other conventional method. First, an empty package is placed on a balance and weighed. The total package volume is determined by completely filling the package with deionized water and determining the deionized water weight and recording it as ( $V_{total}$ ). The package is then filled with a personal care composition leaving a headspace. Next, the package is placed on a balance and re-zeroed. The headspace volume is filled with deionized water by a syringe.



The weight of deionized water filled in the headspace is recorded as ( $V_{\text{headspace}}$ ). The headspace is calculated as:  $V_{\text{headspace}} / V_{\text{total}} * 100\%$ .

“Hydrophobic benefit agent” as used herein, refers to one or a combination of hydrophobic benefit materials that deliver one or more benefits including skin conditioning, skin moisturization, and skin health benefits. The term "lipid" is used herein in reference to hydrophobic benefit agents. In accordance with some embodiments, hydrophobic benefit agents are selected from the group consisting of petrolatum, lanolin, derivatives of lanolin (non-limiting examples include lanolin oil, isopropyl lanolate, acetylated lanolin, acetylated lanolin alcohols, lanolin alcohol linoleate, lanolin alcohol riconoleate) hydrocarbon oils (e.g. mineral oil) natural and synthetic waxes (non-limiting examples include micro-crystalline waxes, paraffins, ozokerite, lanolin wax, lanolin alcohols, lanolin fatty acids, polyethylene, polybutene, polydecene, pentahydrosqualene) volatile or non-volatile organosiloxanes and their derivatives (non-limiting examples include dimethicones, cyclomethicones, alkyl siloxanes, polymethylsiloxanes, methylphenylpolysiloxanes), natural and synthetic triglycerides (non-limiting examples include castor oil, soy bean oil, sunflower seed oil, maleated soy bean oil, safflower oil, cotton seed oil, corn oil, walnut oil, peanut oil, olive oil, cod liver oil, almond oil, avocado oil, palm oil, sesame oil), and combinations thereof.

“Liquid” as used herein means that the composition is generally flowable to some degree. “Liquids,” therefore, may include liquid, semi-liquid, cream, lotion or gel compositions intended for topical application to skin. The compositions may exhibit a viscosity of equal to or greater than about 1,500 (centipoise, hereinafter “cps”), equal to or greater than about 5,000 cps, equal to or greater than about 10,000 cps or equal to or greater than about 20,000 cps and no more than about 1,000,000 cps, no more than about 500,000 cps, no more than about 300,000 cps, or no more than about 200,000 cps as measured by the T-Bar Viscosity Method described hereinafter.

"Lathering Agent" as used herein refers to a surfactant, which when combined with water and mechanically agitated generates a foam or lather sufficient to cause a personal care composition to provide a lather, and which, when tested using the Total Lather Volume Method disclosed herein, yield lather volumes in the range from 800 ml to more than 1500 ml.

“Package” includes any suitable container for personal care compositions exhibiting a viscosity from about 1,500 centipoise (cP) to about 1,000,000 cP, including but not limited to a bottle, tottle, tube, jar, non-aerosol pump and mixtures thereof.

"Personal care article" as used herein, refers to a delivery means (such as a "Package") comprising a "personal care composition."

“Personal care composition” as used herein, refers to compositions intended for topical application to the skin or hair. The compositions used in accordance with the present disclosure are rinse-off formulations, in which the product is applied topically to the skin or hair and then is subsequently rinsed within minutes from the skin or hair with water, or otherwise wiped off using a substrate with deposition of a portion of the composition. The compositions also may be used as shaving aids. The personal care composition used in accordance with the present disclosure is typically dispensible from a package. Thus, in some embodiments, the dispensing may be by extruding. In some embodiments the package may be a single chamber package, or a multi chamber package, or a set of discrete packages. The personal care compositions used in accordance with the present disclosure can be in the form of liquid, semi-liquid, cream, lotion or gel compositions intended for topical application to skin. Examples of personal care compositions used in accordance with the present disclosure can include but are not limited to shampoo, conditioning shampoo, hair conditioner, body wash, moisturizing body wash, shower gels, skin cleansers, cleansing milks, hair and body wash, in shower body moisturizer, pet shampoo, shaving preparations and cleansing compositions used in conjunction with or applied to a disposable cleansing cloth. The product forms contemplated for purposes of defining the compositions and methods as disclosed herein are rinse-off formulations by which it is meant that the product is applied topically to the skin or hair and then subsequently (i.e., such as within minutes) rinsed away with water, or otherwise wiped off using a substrate or other suitable removal means.

"Stage" as used herein refers to a distinguishable part in a cycle of treatment or application of a personal care product according to the disclosure herein. For purposes hereof, a stage need not be limited to a particular period of time. Stages are distinct from one another in that the properties, most particularly the ratio of lathering agent to hydrophobic benefit agent, of a personal care composition vary between sequential stages. Thus, in a cycle comprising three stages of treatment or application, each stage may involve use of personal care compositions that vary relative to one another, for example wherein the ratio of lathering agent to hydrophobic benefit agent varies between each of the stages. In another example, in

a cycle comprising three stages of treatment or application, two of the stages may involve use of personal care compositions that do not vary relative to one another while a third stage varies from the other two. In yet another example in a cycle comprising two stages of treatment or application, each stage may involve use of personal care compositions that vary relative to one another, for example wherein the ratio of lathering agent to hydrophobic benefit agent varies between each of the stages. The terms "Premium Experience Stage" refers to stages in which the components in a personal care composition are associated with delivery of one or more experiential benefits to the user at the time of use, such as lathering and delivery of scent for excellent in-use characteristics during cleansing process. The term "Conditioning Stage" refers to stages in which the components in a personal care composition are associated with delivery of one or more benefits during use, for example, deposition of hydrophobic benefit agent on the skin, that provide long term benefits after use.

"Sagging" as used herein means the laxity, slackness, or the like condition of skin that occurs as a result of loss of, damage to, alterations to, and/or abnormalities in dermal elastin, muscle and/or subcutaneous fat.

"Signs of aging" include, but are not limited to, all outward visibly and tactilely perceptible manifestations as well as any other macro or micro effects due to skin aging. Such signs may be induced or caused by intrinsic factors or extrinsic factors (such as chronological aging and/or environmental damage). These signs may result from processes which include, but are not limited to, the development of textural discontinuities such as wrinkles and coarse deep wrinkles, fine lines, skin lines, crevices, bumps, large pores (e.g., associated with adnexal structures such as sweat gland ducts, sebaceous glands, or hair follicles), or unevenness or roughness, loss of skin elasticity (loss and/or inactivation of functional skin elastin), sagging (including puffiness in the eye area and jowls), loss of skin firmness, loss of skin tightness, loss of skin recoil from deformation, discoloration (including undereye circles), blotching, sallowness, hyperpigmented skin regions such as age spots and freckles, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown, and other histological changes in the stratum corneum, dermis, epidermis, the skin vascular system (e.g., telangiectasia or spider vessels), and underlying tissues (e.g., fat and/or muscle), especially those proximate to the skin.

"Skin," as used herein, refers to keratin-containing layers disposed as the outermost protective covering of mammals (e.g., humans, dogs, cats, etc.) which includes, but is not limited to, skin, mucosa, lips, hair, toenails, fingernails, cuticles, hooves, etc.

“Smoothing” and “softening” as used herein mean altering the surface of the skin such that its tactile feel is improved.

"Stratum corneum," as used herein, refers to the outermost layer of the epidermis and is the skin structure that provides a chemical and physical barrier between the body of an animal and the environment. Skin is divided into two main structural layers, the dermis and the epidermis. The epidermis, in turn, is divided into five strata, which include the: stratum corneum, stratum granulosum, stratum spinosum, and stratum basale. The predominant cell type of the epidermis is the keratinocyte. These cells are formed in the basal layer and exist through the epidermal strata to the granular layer at which they transform into the cells known as corneocytes or squames that form the stratum corneum. During this transformation process, the nucleus is digested, the cytoplasm disappears, the lipids are released into the intercellular space, keratin intermediate filaments aggregate to form microfibrils, and the cell membrane is replaced by a cell envelope made of cross-linked protein with lipids covalently attached to its surface. Thus, keratins are the major structural proteins of the stratum corneum. Corneocytes regularly slough off (a process known as desquamation) to complete an overall process that takes about a month in healthy human skin. In stratum corneum that is desquamating at its normal rate, corneocytes persist in the stratum corneum for approximately 2 weeks before being shed into the environment. The stratum corneum is a densely packed structure comprising an intracellular fibrous matrix that is hydrophilic and able to trap and retain water. The intercellular space is filled with lipids formed and secreted by keratinocytes and which provide a diffusion pathway to channel substances with low solubility in water. A commonly espoused skin metaphor portrays the stratum corneum as a brick wall wherein each brick is a corneocyte and the intercellular matrix is the mortar.

“Surfactant component” as used herein means the total of all anionic, nonionic, amphoteric, zwitterionic and cationic surfactants in a phase. When calculations are based on the surfactant component, water and electrolyte are excluded from the calculations involving the surfactant component, since surfactants as manufactured typically are diluted and neutralized.

"Statically stable" as used herein, unless otherwise specified, refers to a personal care article that comprise at least two compositions that maintain at least two "separate" zones with at least two separate benefit concentrations zones contained within a single chamber package at ambient conditions for a period of at least about 180 days. Alternatively, static stability can be determined by accelerated protocol at elevated temperature. One accelerated

protocol is based on passing static stability after 10 days at 50°C. By "separate" is meant that there is substantially no mixing of compositions contained in the zones, detected by the benefit analysis method, described hereinafter, prior to dispensing of the composition.

"Structured," as used herein means having a rheology that confers stability on the personal care composition. The degree of structure is determined by characteristics determined by one or more of the following methods the Yield Stress Method, or the Zero Shear Viscosity Method or by the Ultracentrifugation Method, all in the Test Methods below. Accordingly, a surfactant phase of the composition used in accordance with the present disclosure is considered "structured," if the surfactant phase has one or more of the following properties described below according to the Yield Stress Method, or the Zero Shear Viscosity Method or by the Ultracentrifugation Method. A surfactant phase is considered to be structured, if the phase has one or more of the following characteristics:

A. a Yield Stress of greater than about 0.1 Pascal (Pa), more typically greater than about 0.5 Pa, even more typically greater than about 1.0 Pa, still more typically greater than about 2.0 Pa, still even more typically greater than about 3 Pa, and even still even more typically greater than about 5 Pa as measured by the Yield Stress and Zero Shear Viscosity Method described hereafter:

B. a Zero Shear Viscosity of at least about 500 Pascal-seconds (Pa-s), typically at least about 1,000 Pa-s, more typically at least about 1,500 Pa-s, even more typically at least about 2,000 Pa-s; or

C. a Structured Domain Volume Ratio as measured by the Ultracentrifugation Method described hereafter, of greater than about 40%, typically at least about 45%, more typically at least about 50%, more typically at least about 55%, more typically at least about 60%, more typically at least about 65%, more typically at least about 70%, more typically at least about 75%, more typically at least about 80%, even more typically at least about 85%.

"Topical application", "topically", and "topical", as used herein, mean to apply (e.g., spread, spray) the compositions used in accordance with the present disclosure onto the surface of the skin.

"Tottle" as used herein refers to a bottle which rests on the neck or mouth which its contents are filled in and dispensed from, but it is also the end upon which the bottle is intended to rest or sit upon for storage by the consumer and/or for display on the store shelf, as described in the commonly owned U.S. Patent Application Serial No, 11/067443 filed on

Feb. 25, 2005 to McCall et al, entitled "Multi-phase Personal Care Compositions, Process for Making and Providing, and Article of Commerce."

"Treating" or "treatment" or "treat" as used herein includes regulating and/or immediately improving skin cosmetic appearance and/or feel. As used herein, "regulating" or "regulation" means maintaining or improving the health and/or cosmetic appearance, and includes both prophylactically regulating and/or therapeutically regulating. Regulation of skin condition, namely mammalian and in particular human skin, hair, or nail condition, is often required due to conditions which may be induced or caused by factors internal and/or external to the body. Examples include environmental damage, radiation exposure (including ultraviolet radiation), chronological aging, menopausal status (e.g., post-menopausal changes in skin, hair, or nails), stress, diseases, disorders, etc. For instance, "regulating skin, hair, or nail condition" includes prophylactically regulating and/or therapeutically regulating skin, hair, or nail condition, and may involve one or more of the following benefits: thickening of skin, hair, or nails (e.g., building the epidermis and/or dermis and/or sub-dermal [e.g., subcutaneous fat or muscle] layers of the skin, and where applicable the keratinous layers of the nail and hair shaft) to reduce skin, hair, or nail atrophy, increasing the convolution of the dermal-epidermal border (also known as the rete ridges), preventing loss of skin or hair elasticity (loss, damage and/or inactivation of functional skin elastin) such as elastosis, sagging, loss of skin or hair recoil from deformation; melanin or non-melanin change in coloration to the skin, hair, or nails such as under eye circles, blotching (e.g., uneven red coloration due to, e.g., rosacea) (hereinafter referred to as "red blotchiness"), sallowness (pale color), discoloration caused by telangiectasia or spider vessels, and graying hair.

"Zone" as used herein refers to a domain or region within a single chamber package which corresponds to a composition of the personal care article. The interface between the zones can be distinct or gradual or separated by another zone. The amount contained within a zone can be defined by a percentage of the package volume and a zone comprises at least 10% of the package volume of a given package, excluding the volume of the package corresponding to the necessary headspace or void volume and the closure, FIG. 14A and FIG. 14B as disclosed herein. In one aspect, the first personal care composition, the second personal care composition and third personal care compositions within a the first zone, second zone or third zone is homogeneous. In this case, the concentration of hydrophobic benefit material is constant within the zone. In another aspect, the personal care composition within the first, second or third zone is inhomogeneous, such that the concentration of

hydrophobic benefit material varies within the zone. The level of hydrophobic benefit material can show an increasing or decreasing trend.

All percentages, parts and ratios are based upon the total weight of the compositions used in accordance with the present disclosure, unless otherwise specified. All such weights as they pertain to listed ingredients are based on the active level and, therefore; do not include solvents or by-products that may be included in commercially available materials, unless otherwise specified. The term "weight percent" may be denoted as "wt. %" herein. Except where specific examples of actual measured values are presented, numerical values referred to herein should be considered to be qualified by the word "about."

All molecular weights as used herein are weight average molecular weights expressed as grams/mole, unless otherwise specified.

## II. Methods and Regimens for Treating Skin

The personal care compositions used in accordance with the present disclosure are used in a conventional manner for cleansing and conditioning skin. The personal care compositions used in accordance with the present disclosure are typically applied topically to the desired area of the skin in an amount sufficient to provide effective delivery of the skin cleansing agent, hydrophobic material, and in some embodiments particles and other agents and actives to the applied surface. The compositions can be applied directly to the skin or indirectly via the use of a cleansing puff, washcloth, sponge or other implement. The compositions are typically diluted with water prior to, during, or after topical application, and then subsequently the skin is rinsed or wiped off, typically rinsed off of the applied surface using water or a water-insoluble substrate in combination with water.

The present disclosure is therefore also directed to methods of cleansing the skin through the above-described application of the compositions as disclosed herein. An effective amount of the composition for cleansing and conditioning the skin is applied to the skin, that in some examples has been wetted with water, and then rinsed off. Such effective amounts generally range from about 1 gm to about 50 gm, and from about 1 gm to about 20 gm.

In general, a typical method for cleansing and conditioning the skin comprises the steps of: a) wetting the skin with water, b) applying an effective amount of the personal care composition to the skin, and c) rinsing the applied areas of skin with water. These steps can be repeated as many times as desired to achieve the desired cleansing and conditioning benefit.

### Treatment Regimens

The present disclosure is directed in various aspects to methods and regimens for cleansing and conditioning skin and for maintaining the quality of skin through use of rinse-off personal care compositions. In some aspects, the methods are useful for sustaining consumer use of a treatment for skin. In accordance with various embodiments, the methods comprise delivery of two or more skin active or benefit agents to the skin of a user, particularly lathering and hydrophobic benefit agents, to provide resulting benefits from such delivery, as described herein. The personal care compositions are formulated in various embodiments with sufficient amounts of each of the benefit agents to provide one or both of superior/premium lather performance and stability and superior/premium hydrophobic benefit agent deposition for extended conditioning. Superior lather performance can be demonstrated via the lather volume test method described herein. Superior hydrophobic benefit agent deposition and associated extended skin conditioning can be demonstrated via the various physical tests and biomarker tests described herein below.

FIG. 1 shows an exemplary profile of lathering agent to hydrophobic benefit agent. As can be seen, one curve describes the dispensing and delivery profile of hydrophobic benefit agent and one curve describes the dispensing and delivery profile of lathering agent over a series of aliquots from a representative article containing 250 ml of product according to the instant disclosure. Of course it will be appreciated that other volumes of product are contemplated, and that the ratio of lathering agent to hydrophobic benefit agent may vary depending on the package features and the fill profile of hydrophobic benefit agent to lathering agent. It will also be appreciated that, as described further herein below that additional benefit agents may be included and as such, any such additional agent may follow the profile of either the hydrophobic benefit agent or the lathering agent or may have a different profile.

In some embodiments, the compositions can comprise additional benefit agents, such as fragrances, exfoliates/desquamates, lightening and other optional agents as further described herein. It is contemplated according to the various embodiments that the two or more skin benefit agents are delivered in varying relative quantities, as more fully described herein below. It will be appreciated that additional benefit agents may be delivered together with one or the other benefit agents such that quantities of such additional benefit agents varies synchronously with one of the other benefit agents. It will further be appreciated that



each of two, three or more benefit agents may each be delivered in varying relative quantities that are not in synchrony with any of the other benefit agents.

The personal care compositions used in accordance with the embodiments disclosed herein are typically liquid or semi-liquid compositions intended for topical application to the hair or skin. Thus, the compositions are "rinse-off" formulations, by which is meant the product is applied topically to the hair or skin and then subsequently and immediately (i.e., within minutes) rinsed away with water, or otherwise wiped off using a substrate or other suitable removal means. The compositions contain at least one lathering agent and at least one hydrophobic benefit agent, both of which are described in greater detail hereinafter. The personal care compositions are applied topically to the desired area of the skin or hair in an amount sufficient to provide effective delivery of the skin benefit agents to the applied surface, or to otherwise provide effective skin conditioning benefits. The compositions can be applied directly to the skin or indirectly via the use of a cleansing puff, washcloth, sponge or other implement. The compositions are in some embodiments diluted with water prior to, during, or after topical application.

Examples of application and use of some embodiments of personal care compositions are provided herein. Likewise, examples describing the methods for characterizing the premium benefits of the compositions, and for preparing and packaging embodiments of the compositions are provided in the examples sections hereof.

In various embodiments, the methods and regimens comprise use of a personal care composition that comprises at least two skin active or benefit agents, typically a lathering agent (surfactant) and a hydrophobic benefit agent (lipid), wherein the amounts (ratio, by weight) of lathering agent to hydrophobic benefit agent vary over the course of the regimen. The composition is used over a period of time, alternately referred to as a treatment cycle or treatment time, that includes two or more sequential stages. It should be understood that the term "stage," as used to describe the methods herein, is intended to be non-limiting with respect to time or sequence of the steps of a treatment cycle. In some embodiments, the treatment cycle includes three stages.

In the various embodiments, the ratio of the lathering agent to the hydrophobic benefit agent varies from one stage to the next stage, wherein in some embodiments the ratio of lathering agent to hydrophobic benefit agent is greater in a first stage than in a second stage. In other embodiments, the ratio of lathering agent to hydrophobic benefit agent is lower in a

first stage than it is in a second stage. In some embodiments comprising three stages, the ratio of lathering agent to hydrophobic benefit agent is higher in a first stage, declines in a second stage, and increases in a third stage. It will be appreciated that a treatment cycle can include two, three, four or more stages, and that the ratio of lathering agent to hydrophobic benefit agent can vary in a variety of ways between each of the sequential stages, as is described more fully herein below.

In accordance with the various embodiments, the methods include the steps of applying the composition to a user's skin on a daily basis for a period of days comprising, in any order, a premium experience stage wherein the ratio of lathering agent to hydrophobic benefit agent is high, the premium experience stage characterized by maximal delivery of lather and scent, and a conditioning stage wherein the ratio of lathering agent to hydrophobic benefit agent is low, the conditioning stage characterized by maximal hydrophobic benefit agent deposition. In some embodiments the sequence of the stages is the premium experience stage followed by the conditioning stage. In other embodiments, the sequence of the stages is the conditioning stage followed by the premium experience stage. In yet other embodiments, the sequence of the stages is a premium experience stage, followed by a conditioning stage, followed by a premium experience stage. It will be appreciated that in some embodiments, each of the benefit agents is present through all stages and that, as described herein, additional benefit agents may be present. In some alternate embodiments one or more benefit agents may be reduced to negligible amounts in one or more stages. According to the various embodiments, the methods include the steps of first applying a first aliquot of the personal care composition to a user's skin together with water, wherein the lathering agent provides lather when contacted on the user's skin with water, and then rinsing the personal care composition from the user's skin, wherein a portion of the hydrophobic benefit agent is deposited and remains on the user's skin after rinsing.

According to a representative embodiment comprising a treatment cycle of three stages, a first stage is a premium experience stage in which a high lathering agent (surfactant) is used that provides a premium user experience through high lather. Thus, in this first stage, the ratio of lathering agent to hydrophobic benefit agent is high relative to the following stage. According to this representative embodiment, as use progresses into a second stage, a high lipid "plateau" provides conditioning through high hydrophobic benefit agent content. Thus, in this second stage, the ratio of lathering agent to hydrophobic benefit agent is low relative to a first stage. And in a third stage a high lathering agent (surfactant) is used that

provides a premium user experience through high lather. Thus, in this third stage, the ratio of lathering agent to hydrophobic benefit agent is high relative to the previous stage.

It will be appreciated that the number and sequential order of premium experience and conditioning stages may vary. As mentioned above, in some embodiments a treatment period may comprise only two stages, or it may comprise three or more stages. Irrespective of the number and order of stages, a treatment cycle is characterized as comprising in any order at least one premium experience stage and one conditioning stage.

According to the various embodiments, personal care compositions provide a lathering agent that produces a lather volume that varies with the varied ratios of lathering agent and hydrophobic benefit agent. In some embodiments the lather volume of the composition is greater than from about 800ml to 1500ml, as tested according to the Lather Volume method described herein. It will thus be appreciated by those in the art that in accordance with the described method, the lather volume provided by a personal care composition may be greater than from about 800, 850, 900, 950, 1000, 1050, 1100, 1150, 1200, 1250, 1300, 1350, 1400, 1450, and 1500 or more ml as well as all points subsumed therein. Of course it will be appreciated that in some embodiments, particularly with respect to embodiments and stages wherein the ratio of lathering agent to hydrophobic benefit agent is low, that the lather volume will be lower or substantially lower than the above stated ranges. In some embodiments the lather volume may be greater than the above ranges, such as from about 1500 to 1750, about 1750 to 1900, about 1900 to 2000 or more ml, as well as all points subsumed therein. It will also be appreciated that other methods described or otherwise known in the art may be used to characterize lather and lather volume and that the description herein is not limiting, such that the lather properties of the compositions used as described herein may be described in other terms.

Optionally, the composition used in accordance with the methods may comprise an additional benefit agent, for example a fragrance. In some embodiments the fragrance agent is delivered with the lathering agent such that the premium experience stage is further characterized by delivery of fragrance. Of course, in other embodiments, the additional agent, such as a fragrance agent, may be delivered with the hydrophobic benefit agent so as to provide enhanced experience during the conditioning stage. And of course in yet other embodiments, the additional benefit agent, such as a fragrance agent, may be delivered in with both the lathering and the hydrophobic benefit agents. In some embodiments, more

than one additional benefit agents, such as two fragrance agents, may be included and the amount or presence of each may vary through the stages. According to the various embodiments comprising additional benefit agent(s), the additional benefit agent(s) may be provided in a fixed amount or concentration, or in amounts that vary across the stages, or that vary with one or the other of the lathering and hydrophobic benefit agents, or that vary separately from each of the other benefit agents. Variation of delivery of benefit agents is more fully described herein below.

According to the various embodiments, the composition as applied during a first stage that comprises a first of the varying ratios of lathering agent to hydrophobic benefit agent, and the composition as applied during a second stage comprises a second of the varying ratios of lathering agent to hydrophobic benefit agent. As described above, in some embodiments, the second ratio of lathering agent to hydrophobic benefit agent is lower than the first ratio. In some embodiments, a treatment cycle comprises a third stage, and the composition as applied therein comprises a third of the varying ratios of lathering agent to hydrophobic benefit agent.

Some embodiments include the steps of dispensing from a personal care article a personal care composition that comprises a lathering agent and a hydrophobic benefit agent, wherein the article operates to dispense the composition in aliquots, and wherein the ratio of lathering agent to hydrophobic benefit agent varies in successively dispensed aliquots of the composition over the course of dispensing the article contents such that the amount of each of the lathering and hydrophobic benefit agents in two or more successive aliquots is different. In some embodiments, every aliquot provided to the user also has another benefit agent, such as a fragrance agent, that may be delivered, for example, with the lathering agent such that its amount varies with the amount of the lathering agent.

In accordance with varying embodiments, the methods and regimens involve the use of personal care compositions provided in one or more delivery articles. In some embodiments the ratios of the lathering agent to hydrophobic benefit agent in the composition vary as a function of containment location in the single delivery article. In some embodiments the composition is contained within discrete zones of the delivery article and wherein ratios of lathering agent to hydrophobic benefit agent are different in each zone. According to such embodiments, the discrete zones are physically separated chambers defined in the delivery article. In some embodiments the personal care composition is

provided in a delivery article adapted to dispense the composition in discrete aliquots of approximately equal volume. In some such embodiments, the delivery article contains sufficient composition for a predetermined application period. In some embodiments aliquots of the composition are dispensed and applied until the contents of the delivery article are substantially depleted.

In some embodiments the ratios of the lathering agent to hydrophobic benefit agent in the composition vary continuously from a first stage through a third stage. It will be appreciated that the variation across a stage or stages may be influenced by the number of aliquots of composition provided. In some embodiments, two or more sequential aliquots of provided composition may be the same with respect to the ratio of lathering agent to hydrophobic benefit agent. In other embodiments, each aliquot may have the same ratio of lathering agent to hydrophobic benefit agent.

In accordance with some embodiments, the composition is provided in a delivery article that contains sufficient composition for at least one treatment cycle. According to such embodiments, the delivery article is adapted to dispense the composition in discrete aliquots, and wherein aliquots of the composition are applied until the contents of the delivery article are substantially depleted. In some embodiments, each aliquot dispersed has the same approximate volume. In some embodiments, the volume of each successively dispensed aliquot increases or decreases. In some embodiments, a first dispensed aliquot comprises a first ratio of varying ratios of lathering agent to hydrophobic benefit agent, and a subsequently dispensed aliquot comprises a second ratio of the varying ratios, the third ratio being different from the first ratio. According to such embodiments, an aliquot dispensed subsequent to the second aliquot comprises a third ratio of the varying ratios, the third ratio being different from the second ratio. In some embodiments, an aliquot dispensed subsequent to the second aliquot comprises a third ratio of the varying ratios, the third ratio being different from the first ratio. In some embodiments, an aliquot dispensed subsequent to the second aliquot comprises a third ratio of the varying ratios, the third ratio being different from the first and second ratios.

FIG. 2 and FIG. 3 each show representative dispensing profiles in dose increments for the lipid (hydrophobic benefit agent) in the variable lipid product of the present disclosure. FIG. 2 shows a profile dispensed from a 250 ml article and FIG. 3 shows a profile dispensed from a 450 ml article, each for a composition comparable to Inventive Example B described

in Tables 5, 6 and 7. Of course it will be appreciated that other volumes of product are contemplated, and that the percentage of hydrophobic benefit agent may vary as described further herein, and depending on the package features and the fill profile of hydrophobic benefit agent to lathering agent.

It will thus be appreciated that when the composition is provided in a single package, the relative amount (ratio) of each of the lathering agent and hydrophobic benefit agent varies by weight throughout the package. Thus, according to such embodiments, in a package having a first end and a second end, the relative amounts of each of the benefit agents will vary from the first end to the second end. In some embodiments the ratios may vary continuously such that the ratio changes incrementally from one end to the other end. According to such embodiments, the composition within the package is characterized by at least two zones, wherein in one zone the ratio of the lathering agent to the hydrophobic benefit agent is high and in another zone the ratio of the lathering agent to the hydrophobic benefit agent is low, and wherein the ratio of lathering agent to hydrophobic benefit agent varies continuously through the package and thus within and between the zones or regions. According to some embodiments, the composition within the package is characterized by at least three zones, wherein in a first zone the ratio of the lathering agent to the hydrophobic benefit agent is high and in an adjacent second zone the ratio of the lathering agent to the hydrophobic benefit agent is low, and in an adjacent third zone the ratio of lathering agent to hydrophobic benefit agent is high, and wherein the ratio varies continuously through the package and thus within and between zones or regions. In alternate embodiments the ratios may vary discretely such that the ratio is constant through a zone or region, and in an adjacent zone or region the ratio is different.

In some embodiments, the package or delivery article comprises discrete zones of the composition, each zone having ratios of lathering agent to hydrophobic benefit agent, In some embodiments, each zone comprises a plurality of ratios of lathering agent to hydrophobic benefit agent, said plurality of ratios being different from the plurality of ratios of the adjacent zone. In some embodiments, at least one zone comprises a single ratio of lathering agent to hydrophobic benefit agent, and the adjacent zone comprises a plurality of ratios lathering agent to hydrophobic benefit agent.

In accordance with various embodiments, the ratio of lathering agent to hydrophobic benefit agent may vary in each stage across a broad possible range. In some embodiments,

the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 75:25 during a first stage, and the ratio of lathering agent to hydrophobic benefit agent is at a minimum of about 45:55 during a second stage, and the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 75:25 during a third stage. Thus, in each of these consecutive exemplary stages, the amount of lathering agent may be referred to as "high" in a first stage, "low" in a second stage and "high" in a third stage, and the amount of hydrophobic benefit agent may be referred to as "low" in a first stage, "high" in a second stage, and "low" in a third stage. Correspondingly, then a first stage may be referred to as a premium experience stage, a second stage may be referred to as a conditioning stage, and a third stage may be referred to as a premium experience stage.

As more fully described herein, it will be apparent that the actual ratios or ranges of ratios in each of the premium experience stages may be the same or different from each other, and likewise the actual ratios or ranges of ratios in each of the conditioning stages may be the same or different from each other. It will also be apparent that the terms "high" and "low" as well as analogous qualitative terms including "greater than," "less than," "maximum," "minimum" and "peak," are all relative with respect to the ratios of lathering agent to hydrophobic benefit agent of the composition as it is used in sequential stages. Thus, in accordance with the various ratios of lathering agent to hydrophobic benefit agent that are described herein, the greater the amount of lathering agent, the greater the experience in terms of lather volume, and optional properties such as fragrance delivery or other benefits. And the greater the amount of hydrophobic benefit agent, the greater the deposition of lipid during the conditioning stage.

In some embodiments, the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 70:30 during a first stage, and the ratio of lathering agent to hydrophobic benefit agent is at a minimum of about 45:55 during a second stage, and the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 80:20 during a third stage. In some embodiments, the ratio of lathering agent to hydrophobic benefit agent is at a maximum in the range from about 50:50 to 90:10 during a first stage, and the ratio of lathering agent to hydrophobic benefit agent is at a minimum in the range from about 10:90 to 50:50 during a second stage, and the ratio of lathering agent to hydrophobic benefit agent is at a maximum in the range from about 50:50 to 90:10 during a third stage.

It will be appreciated that the variations in ratios in each stage and between the stages may vary independently of the interval time of treatment, and that the number of days of

treatment during any stage in a described interval may vary. Further, it will be appreciated that the number of aliquots or units of composition dispensed or used in a treatment cycle, during any stage, or in any single application may vary, and that the volume of aliquots may vary.

Suitable aliquots for application during a first stage include, but are not limited to, those having a ratio of lathering agent to hydrophobic benefit agent from about 90:10 to about 50:50. Accordingly, non-limiting examples of suitable aliquots for application during a first stage are those having ratios of 90:10, 85:15, 80:20, 75:25, 70:30, 65:35, 60:40, 55:45, and 50:50. In some embodiments, at least every other aliquot dispensed and applied during the first stage has a lower ratio of lathering agent to hydrophobic benefit agent. In some embodiments, at least every other aliquot dispensed and applied during the first stage has the same ratio of lathering agent to hydrophobic benefit agent.

Suitable aliquots for application during a second stage include, but are not limited to, those having a ratio of lathering agent to hydrophobic benefit agent from about 50:50 to about 10:90. Accordingly, non-limiting examples of suitable aliquots for application during a second stage are those having ratios of 50:50, 45:55, 40:60, 35:65, 30:70, 25:75, 20:80, 15:85, and 10:90. In some embodiments, at least every other aliquot dispensed and applied during the second stage has a lower ratio of lathering agent to hydrophobic benefit agent. In some embodiments, at least every other aliquot dispensed and applied during the second stage has the same ratio of lathering agent to the hydrophobic benefit agent.

Suitable aliquots for application during a third stage include, but are not limited to, those having a ratio of lathering agent to hydrophobic benefit agent from about 50:50 to about 90:10. Accordingly, non-limiting examples of suitable aliquots for application during a third stage are those having ratios of 50:50, 55:45, 60:40, 65:35, 70:30, 75:25, 80:20, 85:15, and 90:10. In some embodiments, at least every other aliquot dispensed and applied during the third stage has a higher ratio of lathering agent to hydrophobic benefit agent.

In some embodiments, the composition comprises discrete zones having varying ratios of lathering agent to hydrophobic benefit agent, and each aliquot dispensed to the user during a stage has the same ratio. For example, the composition may be in discrete zones within the package, each zone having a different ratio of lathering agent to hydrophobic benefit agent. As a further example, each zone may correspond to a stage of the treatment regimen. In the embodiments wherein the composition comprises zones of discrete ratios of lathering agent to hydrophobic benefit agent, suitable aliquots for application during a first stage include, but



are not limited to, those having a ratio from about 90:10 to about 50:50. Accordingly, non-limiting examples of suitable aliquots for application during a first stage are those having ratios of 90:10, 85:15, 80:20, 75:25, 70:30, 65:35, 60:40, 55:45, and 50:50.

In the embodiments wherein the composition comprises discrete zones having ratios of lathering agent to hydrophobic benefit agent, suitable aliquots for application during a second stage include, but are not limited to, those having a ratio from about 50:50 to about 10:90; and all points subsumed therein. Accordingly, non-limiting examples of suitable aliquots for application during a second stage are those having ratios of 50:50, 45:55, 40:60, 35:65, 30:70, 25:75, 20:80, 15:85, and 10:90. In the embodiments wherein the composition comprises discrete ratios of lathering agent to hydrophobic benefit agent, suitable aliquots for application during a third stage include, but are not limited to, those having a ratio from about 50:50 to about 90:10. Accordingly, non-limiting examples of suitable aliquots for application during a third stage are those having ratios of 50:50, 55:45, 60:40, 65:35, 70:30, 75:25, 80:20, 85:15, and 90:10.

In accordance with the provided methods, the composition is provided in a delivery article that is adapted for use in accordance with a predetermined time of treatment or a predetermined approximate number of instances of treatment, or both. Thus, in some embodiments, the delivery article is adapted to deliver sufficient composition for one or two or more treatment cycles. In some embodiments, the delivery article is adapted to deliver the composition for each treatment cycle in an approximate number of aliquots or units. In such embodiments, the aliquots may be the same in volume or may vary. In some embodiments the number of aliquots or units to be dispensed per stage or in a delivery article is a predetermined number that defines the approximate number of instances of use, either in days, weeks or months.

In accordance with some embodiments of the methods, the composition is applied on a daily basis. A delivery article as described above may optionally be used for delivery of the composition. It will be appreciated that treatment times and frequency may vary based upon the user, and as such, treatment may be on a less than daily basis, or may be more often. In other embodiments, the treatments may be less frequent, for example weekly or monthly, or in some other interval of time.

As described herein above with respect to the stratum corneum, that is, the outermost layer of the skin, that the cycle of cell turnover in the epidermis from the basal stratum to the

stratum corneum is on the order of about a month, or from about 27 to 30 days. In addition, the average sloughing (desquamation) time of cells from the stratum corneum is on the order of about two weeks, or from about 12-14 days. It has been appreciated with respect to the methods hereof, that treatment cycles adapted to the biology of the skin are surprisingly effective in improving and maintaining the normal function and healthy quality of skin, as more fully described herein with respect to the characterization of skin properties. Thus, treatment cycles which span the typical epidermal cell cycle (for keratinocytes) and which include at least one conditioning stage of about a week have been demonstrated to be effective, as described herein.

In some embodiments of the methods hereof the composition is applied through a treatment cycle in a time interval of about thirty days. For example, a first stage of the treatment cycle may be from about 3 to 7 days, a second stage of the treatment cycle may be from about 6 to 14 days, and a third stage of the treatment cycle may be from about 6 to 14 days. In another example, a first stage of the treatment cycle may be from about 2 to 5 days, a second stage of the treatment cycle may be from about 3 to 7 days, and a third stage of the treatment cycle may be from about 14 to 21 days. In accordance with these examples, in some embodiments the first and third stages are premium experience stages, wherein the delivery of lathering agent and associated lather volume is high as compared with the second, conditioning stage, wherein the delivery of hydrophobic benefit agent is high.

It will be appreciated that according to the methods, a treatment cycle may be repeated two or more times. According to various embodiments, repeated treatment cycles may have the same number and order of stages and may be of the same length of time. Of course, in other embodiments, sequential treatment cycles may each have different numbers and orders of stages and may be of varying lengths of time. In accordance with a representative embodiment of a treatment cycle as described above, wherein the cycle is about 30 days or one month, the treatment cycle may be repeated one or more times. Thus, in a series of two treatment cycles, there are six stages ordered as premium experience, conditioning, premium experience, premium experience, conditioning, premium experience. As in the example described above, the number of days of each cycle may be as described, or the number of days may be as described in alternate embodiments described below.

In other embodiments, the composition is applied through a treatment cycle in a time interval of about fifty days. In one example, a first stage of the treatment cycle may be from

about 3 to 7 days, a second stage of the treatment cycle may be from about 10 to 28 days, and a third stage of the treatment cycle may be from about 14 to 20 days.

In other embodiments, the applied through a treatment cycle in a time interval of about fifty-six days. In one example, a first stage of the treatment cycle may be from about 2 to 7 days, a second stage of the treatment cycle may be from about 3 to 28 days, and a third stage of the treatment cycle may be from about 6 to 21 days.

In accordance with various embodiments, the composition used in accordance with the methods may include one or more optional additional benefit agents. Non limiting examples of benefit agents includes vitamins, vitamin derivatives, sunscreens, desquamation actives, anti-wrinkle actives, anti-atrophy actives, anti-oxidants, skin soothing agents, skin healing agents, skin lightening agents, skin tanning agents, anti-acne medicaments, essential oils, sensates, pigments, colorants, pearlescent agents, interference pigments, particles, hydrophobically modified non-platelet particles and combinations thereof. Other benefit agents and materials as described herein and those known in the art may also be used with respect to representative composition embodiments described herein. Likewise, other formulation components, including other and additional lathering/surfactant agents and hydrophobic benefit agents may be selected as described herein. Additional benefit agents may be provide with either or both the lathering agent and the hydrophobic benefit agent. Examples of some specific benefit agents include exfoliating agents, niacinamide, vitamin E (tocopherol or tocotrieneol), collagen.

#### Characterization of skin: physical properties and biomarkers

In some embodiments, the quality of a user's skin after a treatment cycle comprising at least one conditioning stage exhibits improvement sufficient to be detected by measurement of one or more physical properties that include: reduction of visual dryness, reduction in trans-epidermal water loss, increased skin hydration, increased elastic extension, increased elastic recovery, and increased firmness, as compared to normal healthy control skin. Also, the quality of a user's skin after a treatment cycle comprising at least one conditioning stage exhibits improvement sufficient to be detected by measurement of one or more biomarker properties of the stratum corneum that include: reduction in total protein, and increase in the

amount of one or more of Keratin 1, Keratin 10 and Keratin 11, as compared to normal healthy control skin.

In some embodiments, effectiveness of treatment is evidenced by detection of variations (or lack thereof) in at least one of biomarker indicators or physical properties of a user's skin after treatment cycle, as compared to normal healthy control skin. In some embodiments, effectiveness of treatment is evidenced by no measurable variations in at least one biomarker indicator or physical property.

In some embodiments, effectiveness of treatment is evidenced by a reduction of visual dryness, wherein the reduction is greater than 0.5 dryness units, as compared to water control. For example, a reduction by from about 0.5 to about 5.0 dryness units, and all points subsumed therein, would be evidence of effectiveness of treatment. Accordingly, a reduction of 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, or 10.0 would be evidence of effectiveness of treatment. An effective reduction of visual dryness may be achieved after a suitable period of time after application of the product. For example, after three hours from application.

In some embodiments, effectiveness of treatment is evidenced by a reduction of trans-epidermal water loss, wherein the reduction is greater than 0.2 TEWL units, as compared to water control. For example, a reduction by from about 0.2 to about 2.0 TEWL units, and all points subsumed therein, would be evidence of effectiveness of treatment. Accordingly, a reduction of 0.2, 0.4, 0.6, 0.8, 1.0, 1.2, 1.4, 1.6, 1.8, or 2.0 would be evidence of effectiveness of treatment. An effective reduction of trans-epidermal water loss may be achieved after a suitable period of time after application of the product. For example, after three hours from application.

In some embodiments, effectiveness of treatment is evidenced by an increase in skin hydration, wherein the increase is greater than one Corneometer Unit, as compared to water control. For example, an increase of from about one to about 20 Corneometer Units, and all points subsumed therein, would be evidence of effectiveness of treatment. Accordingly, an increase of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20 would be evidence of effectiveness of treatment. An effective increase in skin hydration may be achieved after a suitable period of time after application of the product. For example, after three hours from application.

In some embodiments, effectiveness of treatment is evidenced by an increase in elastic extension, wherein the elastic extension improvement index is greater than 5. For example,

an elastic extension improvement index of from about 5 to about 50, and all points subsumed therein, would be evidence of effectiveness of treatment. Accordingly, an elastic extension improvement index of 5, 10, 15, 20, 25, 30, 35, 40, 45, or 50 would be evidence of effectiveness of treatment. An effective increase in elastic extension may be achieved after a suitable period of time after application of the product. For example, after one hour from application.

In some embodiments, effectiveness of treatment is evidenced by an increase in elastic recovery, wherein the elastic recovery improvement index is greater than 5. For example, an elastic recovery improvement index of from about 5 to about 50, and all points subsumed therein, would be evidence of effectiveness of treatment. Accordingly, an elastic recovery improvement index of 5, 10, 15, 20, 25, 30, 35, 40, 45, or 50 would be evidence of effectiveness of treatment. An effective increase in elastic recovery may be achieved after a suitable period of time after application of the product. For example, after one hour from application.

In some embodiments, effectiveness of treatment is evidenced by an increase in skin firmness, wherein the skin firmness improvement index is greater than 4. For example, a skin firmness improvement index of from about 4 to about 20, and all points subsumed therein, would be evidence of effectiveness of treatment. Accordingly, a skin firmness improvement index of 4, 8, 12, 16, or 20 would be evidence of effectiveness of treatment. An effective increase in skin firmness may be achieved after a suitable period of time after application of the product. For example, after one hour from application.

In some embodiments, effectiveness of treatment is evidenced by a reduction in total protein, wherein the total protein improvement index is greater than 5. For example, a total protein improvement index of from about 5 to about 50, and all points subsumed therein, would be evidence of effectiveness of treatment. Accordingly, a total protein improvement index of 5, 10, 15, 20, 25, 30, 35, 40, 45, or 50 would be evidence of effectiveness of treatment. An effective reduction in total protein may be achieved after a suitable period of time after application of the product. For example, after one hour from application.

In some embodiments, effectiveness of treatment is evidenced by an increase in the amount of one or more of Keratin 1, Keratin 10, and Keratin 11, wherein the Keratin improvement index is greater than 20. For example, a Keratin improvement index of from about 20 to about 1000, and all points subsumed therein, would be evidence of effectiveness of treatment. Accordingly, a Keratin improvement index of 20, 40, 60, 80, 100, 120, 140,

160, 180, 200, 220, 240, 260, 280, 300, 320, 340, 360, 380, 400, 420, 440, 460, 480, 500, 520, 540, 560, 580, 600, 620, 640, 660, 680, 700, 720, 740, 760, 780, 800, 820, 840, 860, 880, 900, 920, 940, 960, 980, or 1000 would be evidence of effectiveness of treatment. An effective increase in the amount of one or more of Keratin 1, Keratin 10, and Keratin 11 may be achieved after a suitable period of time after application of the product. For example, after one hour from application.

Thus, in accordance with the various embodiments described herein, the quality of a user's skin may be monitored at one or more intervals through at least one treatment cycle comprising premium experience and conditioning stages, wherein effectiveness of the treatment is evidenced improvement or maintenance of at least one biomarker property alone or together with one or more physical property. It will be appreciated that the physical and biomarker indicators of skin quality are not limited to those identified herein above and that other identifiers or indicators later discovered or currently known in the art may also be assessed to determine maintenance or improvement of skin quality according to the methods hereof.

An unexpected and surprising discovery is reported herein with respect to the characterization of skin treated with a rinse-off personal care composition according to the methods hereof. The discovery is described in more detail in EXAMPLE 2 herein and related figures and tables, which show that after one treatment cycle, measurable and statistically significant improvement in at least one biomarker property is achieved and sustained for several days beyond the conditioning stage. As shown in the example, improvement was shown in each of the tested indicators, at time intervals as indicated.

According to description disclosed in the art, it is known that skin quality is not maintained during sporadic treatment with rinse-off compositions, generally. And it is known that skin quality is not maintained or even improved using rinse-off compositions that comprise relatively low hydrophobic benefit agent, for example compositions comprising ratios of lathering agent to hydrophobic benefit agent that are in the range from more than 90:10 to about 60:40 (by weight). FIG. 4 shows representative results with two different constant lipid products (commercially available) wherein the products provide varying skin conditioning when delivered over a time period of 21 days, with measurements taken for dryness change at days 7, 14 and 21. As shown, only the 50% lipid shows a significant

sustained benefit with continued use as compared with water. In contrast, the 30% lipid shows only a modest improvement over time as compared with water. These results are relevant in the context of the methods and compositions used according to this disclosure. This is because, despite the fact that the relatively brief conditioning stage (as described more fully in Example 2) is followed by a low lipid and high surfactant stage, the measured improvement conferred during the conditioning stage persists well beyond its conclusion and through the end of the subsequent low lipid stage. These results were unexpected.

Exemplary treatment regimens for achieving measurable skin improvement according to one or more biomarkers are characterized as comprising three stages. According to some such embodiments, the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 70:30 during a first stage (a premium experience stage), and the ratio of lathering agent to hydrophobic benefit agent is at a minimum of about 45:55 during a second stage (a conditioning stage), and the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 80:20 during a third stage (a premium experience stage).

Also provided are methods for improving the quality of skin that are evidenced by measurable improvement in one or more biomarker indicators. According to such methods, in some embodiments the steps include dispensing from a personal care article a personal care composition that comprises a hydrophobic benefit agent and a lathering agent in a rinse-off formulation, applying the personal care composition to a user's skin together with water, rinsing the personal care composition from the user's skin, wherein a portion of the hydrophobic benefit agent is deposited and remains on the user's skin after rinsing. According to such embodiments, the steps further include repeating the steps of applying and rinsing on at least a once daily basis over a time interval of successive days, the time interval of use sufficient to permit detection of measurable improvement in at least one biomarker property selected from reduction in total protein, and increase in the amount of one or more of Keratin 1, Keratin 10 and Keratin 11. Optionally, additional characterization may be achieved by measuring one or more physical properties to show improvement in skin condition.

According to the various embodiments, evidence of improvement based on physical properties and biomarkers is determined using general analytic methods known in the art. It will be appreciated, though, that this disclosure is the first reported instance in which measurable improvement in one or more skin biomarkers has been reported in the context of

a rinse-off personal care product. Moreover, it will be appreciated that this is the first reported instance wherein a regimen involving the use of a rinse-off composition having a varied benefit agent profile as described herein has been employed. And thus, this disclosure is the first to report the employment of biomarker and physical property measurements of skin to show measurable improvement in one or more properties after treatment according to the instant disclosure. As more fully described in the examples herein, methods for measuring physical properties and skin biomarkers have been employed to demonstrate the effectiveness of the methods hereof.

#### Formulating Compositions and Methods for Populations

In accordance with some embodiments, a delivery article is adapted to deliver composition formulated to match a population profile, wherein the profile reflects preferences in a population for composition properties selected from maximum hydrophobic benefit agent content, lathering, scent, color, opalescence, thickness, and combinations of these. Methods of identifying population profiles and developing personal care compositions are described herein.

It will be appreciated that the methods hereof are useful for benefiting users from a variety of populations. Accordingly, also provided are methods for developing personal care compositions and regimens of treatment for members of various populations. The methods involve understanding the preferences of the target populations. For example, North American consumers are accustomed to thicker personal care compositions and heavier skin feel than consumers in China. Accordingly, when designing a premium anti-aging body wash and methods of use, the personal care compositions must comply with regional expectations balanced with delivery of the consumer desired skin benefits. Thus, for example, for one target population, the personal care composition lipid profile varies from 25% to 55%, giving consumers not only improved personal care composition aesthetics and in-use experience, but optimal performance in terms of conditioning. For another target population, personal care composition lipid profile varies from 10-15% lipid. Similar preferences exist with respect to personal care composition texture, consistency, lather character and primary benefit focus. For example, while some eastern consumers expect personal care compositions that are of thinner consistency and lighter skin feel, other consumers are more similar to American consumers – expecting more from their personal care compositions, enjoying thicker consistencies and are more open to heavier skin feels. Thus, methods are provided for providing a range of personal



care compositions (a global menu) for the consumers in various populations, such as populations that are defined geographically. Accordingly, in some embodiments, it is possible to utilize a common base formulation of a composition, for example one of the exemplary compositions as described herein below, which may optionally be packaged and suitable for dispensing as described herein, wherein the only variable in production of an article is the ratio of lathering agent to hydrophobic benefit agent during the filling of the article.

The various embodiments include identifying a target population and developing a population profile with respect to a rinse-off personal care composition used for cleansing and moisturizing comprising the steps of determining the population preferences for maximum amount of hydrophobic benefit agent, and determining the population preferences for lather volume, lather texture, and lathering speed, composition thickness, color, translucence, opalescence, and scent. Such embodiments further include the steps of formulating a personal care composition reflecting a population profile, wherein the composition comprises varying ratios of a lathering agent to a hydrophobic benefit agent, configuring a delivery article adapted to dispense the composition in discrete aliquots of approximately equal volume, and adapted to contain the composition so as to dispense the composition in stages comprising at least a first stage comprising a first ratio of the varying ratios of lathering agent to hydrophobic benefit agent, and a second stage comprising a second ratio of the varying ratios of lathering agent to hydrophobic benefit agent that is different than the first ratio. In some such embodiments, the steps further include manufacturing the composition for the target population; and providing the composition in the delivery article. It will be appreciated that the method may be repeated for a different target population.

The following examples further describe and demonstrate embodiments within the scope of the present disclosure. The examples are given solely for the purpose of illustration and are not to be construed as limitations of the present disclosure, as many variations thereof are possible without departing from the spirit and scope hereof.

### III. TREATMENT EXAMPLES

#### EXAMPLE 1: Personal Care Composition Features and Benefits

Table 1 identifies several factors that have been obtained anecdotally to describe the desires or requirements described by consumers in connection with rinse-off personal care compositions. As described herein, an aspect of effective delivery of conditioning to a user of such a personal care composition is the continued use of a product so as to enable sufficient

deposition of hydrophobic benefit agent. Commonly, consumers are inclined to suspend or cease use of products that do not provide a premium experience, despite the fact that such products may deliver conditioning benefits. The described table describes the aspects or factors associated with a use experience and sustained benefits that are desired from a rinse-off product in order to ensure continued use by the consumer.

**Table 1**

Factors	Benefits
1. Skin Enhancement	Minimizing lines Improving skin tone Helping skin look younger
2. Rinsing/Clean Feel	Not leaving skin greasy or coated Rinsing easily from skin Leaving skin feeling clean
3. Moisturization	Not leaving skin dry/cracked Leaving skin soft/smooth Hydrating and locking in Moisture
4. Scent	Having a pleasant scent during use Having a pleasant scent in bottle Leave long lasting scent on skin
5. Lather	Providing right lather amount Lathering quickly and easily Providing rich, creamy lather

EXAMPLE 2: Clinical Study: Evaluation of Skin Indicator Response

A study was undertaken to evaluate the response of a variety of skin indicators using an array of different personal care compositions and water. Leg wash studies are used to evaluate the beneficial effects of personal care products on dry leg skin. Leg wash studies are designed to approximate consumer-relevant exposure levels, e.g. washing frequency. The technique used in this study is a modification of a published procedure (Ertel, et al, 1999).

The study included a product having a variable lipid profile, wherein the ratio of surfactant to lipid (lathering agent to hydrophobic benefit agent) varied continuously between three stages according to the instant disclosure. The study also included a commercially available product having a constant lipid profile. As further described herein below, the compositions used in the study included Inventive Example B and Comparative Example C, as shown in Table 5, and related Tables 6 and 7 (which describe the filler and dispensing profiles for the products).

FIG. 5 shows a representative dispensing profile for the lipid (hydrophobic benefit agent) in the variable lipid product of the present disclosure. The profile indicates with arrows the treatment days at which certain measurements as described herein were made. Thus, the treatment days are shown with reference to the initiation of treatment after the preconditioning interval; day 1 as shown on FIG. 5 corresponds to study day 8, and so on.

The study was 29 days in duration, with a 7 day interval of preconditioning, 21 days of treatment and 1 regression day. Skin was analyzed at various points from the beginning through the end of the study period. The objective of the study was to characterize the dry skin improvement profile of several body wash prototypes and to generate samples to assess treatment's effects on stratum corneum physical and biomarker indicators. After the 7-day preconditioning stage, subjects returned to the test facility to have the skin on their lower legs evaluated by an expert grader. Only subjects which exhibited sufficient dryness on all of the treatment sites qualified to continue into the treatment stage. Technicians treated each qualified subject's lower legs in a controlled manner with the assigned treatments once daily for 21 days. Subjects' legs were visually evaluated for dryness and redness at several pre and post-treatment times as outlined in the following study schedule. Non-invasive instrumental measurements of stratum corneum hydration (Corneometer 825), barrier function (Dermalab TEWL (trans epidermal water loss)), and viscoelasticity (Cutometer) were made on the treatment sites following visual evaluations.

#### Treatment Stage Procedure

Before initial grading on Study Day 8, test facility personnel marked off the leg application areas [two 70cm<sup>2</sup> areas (7cm across X 10cm down)] on the outer aspect of the subjects' lower legs using a template and laboratory marking pen (corner brackets are sufficient to delineate each area). Trained clinical assistants treated each subject's legs according to the procedure outlined in the Treatment Procedure. In general, the following should be noted: The procedure was conducted once each day for 21 consecutive days. The body wash products were applied using puffs (personal cleaning implements). The puff treatment procedure for all puffs was conducted daily after all product treatments were completed on each subject (except on the final day of treatment.).

#### Evaluations

At each evaluation, subjects acclimated for a minimum of 30 minutes in a room with the environment maintained at  $70^{\circ}\text{F} \pm 2$  and 30-45% relative humidity prior to visual grading and non-invasive instrumental measurements being made on their legs.

#### Visual Grading

Each subject's lower legs were visually evaluated by a qualified grader for dryness and redness at baseline (Study Day 8, prior to the first treatment) as a prerequisite for qualification into the treatment stage. Measurements were made thereafter on study days 10, 12, 21, 28 and 29, at approximately 3 hours post treatment. Referring to FIG. 6, comparative results according to the study are shown.

#### Corneometer Skin Capacitance

Non-invasive skin capacitance measurements were taken in duplicate on each site of the subjects' legs after every visual grading during the study using a Corneometer CM825 instrument. Data was recorded electronically using the Sponsor's direct data entry and data capture programs. The same instrument and operator were used throughout the study. Referring to FIG. 7, comparative results according to the study are shown.

#### Trans-epidermal Water Loss (TEWL)

TEWL was measured with the DermaLab® Evaporimeter equipped with dual probes. Each measurement consists of readings collected for 60 seconds with the mean of the last 20 seconds recorded from both probes (Channel A and Channel B). One measurement was taken at each treatment site and recorded on DCF 2 (DermaLab TEWL Measurements Log) on each evaluation day for both probes as Channel A and Channel B, respectively. The same instrument and operator were used throughout the study. These measurements were made according to procedures outlined in accordance with published guidelines. Measurements were taken 8 times during the course of the study on study days 10, 12, 21, 28 and 29, at approximately 3 hours post treatment. Referring to FIG. 8, comparative results according to the study are shown.

#### Cutometer Measurements of Elasticity

Reapplication of methods typically used for facial skin in a leave-on context were used with a cutometer on legs in a rinse-off personal care composition context. Non-invasive skin viscoelasticity measurements were taken with a Cutometer SEM 575 equipped with an 8 mm probe. Data was recorded electronically using the data capture program accompanying

the instrument. Two Cutometer instruments were used due to the number of subjects enrolled in the study. Subjects were assigned to the same instrument throughout the study on the basis of their subject number. The same instruments and operators were used throughout the study. These measurements were made according to the procedures outlined in the Sponsor's instrument SOPs or published guidelines. Measurements were taken 5 times during the course of the study on study days 10, 12, 21, 28 and 29, at approximately 3 hours post treatment. Referring to FIG. 9, FIG. 10 and FIG. 11, comparative results according to the study are shown.

### Tape Stripping

Tape stripping was performed throughout the study for dry skin sampling. D-Squames were always collected following all other evaluations scheduled to take place at the same time point. Clinical assistants wore disposable gloves while collecting D-Squames. At each collection time point a series of 6 D-Squames were used to sample the same spot within the treatment area. The technician used forceps to place a D-Squames sampling disc toward the edges of each site (away from the region being evaluated by other instrumentation) and applied pressure using the D-Squames disc applicator (push the D-Squames applicator down and then release). The technician removed the sampling disc with forceps and placed the disc into a pre-labeled 12 well culture plate. Each subject had two 12 well culture plates for sampling disc collection; one for each leg. Wells 1-6 of each plate were for the site nearest the knee, while wells 7-12 were used for the site nearest the ankle. D-Squames sample plates were placed in shipping boxes with labels corresponding to the subjects' samples enclosed and placed in a cooler with dry ice. D-Squames were collected 4 times at the following time points, on study days 8, 12, 21, and 29, at approximately 3 hours post treatment.

References: Ertel, K.D., Neumann, P. B., Hartwig, P. M., Rains, G. Y., and Keswick, B. H., Leg Wash protocol to assess the skin moisturization potential of personal cleansing products. *Int. J. Cosmet. Sci.* **21**: 383-397 (1999); Fitzpatrick, T.B., The validity and practicality of sun-reactive skin types I through VI. *Arch. Dermatology*, **124**: 869-871 (1988).

### Soluble Protein and Keratin Analyses

Samples were collected for analysis using D-Squame Tape Strips. D-Squame tapes were applied on the leg with constant pressure/time, and removed to collect samples of the stratum corneum. Alternative sampling methods using Sebutape and Cup Scrubs can also be

accommodated. Tape strip samples were placed in a 12 well plate under frozen conditions (-80°C) until analysis. Tape samples were extracted for analysis by placing the tapes inside a polypropylene tube (2 ml) and adding extraction buffer (PBS, pH 7.4, 0.04% SDS, Protease Inhibitors) and sonicating for 30 min at 4°C. The samples were then centrifuged to remove any insoluble material and the supernatant is transferred into two deep well plates.

Supernatant samples for keratin analysis were fortified with 2.0% Bovine Serum Albumin (BSA) before freezing. The remaining supernatants were transferred to a second deep well plate for Soluble Protein analysis. Samples were analyzed for Skin analytes (Human Serum Albumin, Keratin 1,10,11) using validated Millipore™ Multiplex immunoassay methods with a Bio-Plex Protein Array Reader system. Soluble protein determinations of the supernatants were performed using the Pierce BCA™ Protein assay kit with the aliquot designated for soluble protein using a validated method. The values obtained for soluble proteins were used to normalize. Skin analyte concentrations were reported as pg/mL or ng/mL and the soluble proteins were reported as µg/mL. Methods have been validated to demonstrate accuracy, precision, bench top stability, freeze thaw stability, short and long term storage stability of the extracts. Extraction efficiency of the methods have been shown to be >70% and reproducible with a single extraction of the tape strips.

Table 2 shows the physical properties to be assessed in the studies (Endpoints), the biomarkers to be analyzed (Biomarkers), the experimenter's rationale (Rationale) and the expected outcome expected by the experimenters (Expected Biomarker Outcome).

Quite surprisingly, the study showed that delivery of a rinse-off composition having a lipid to surfactant profile that varied over time provided measurable benefits well beyond the stage of high lipid delivery, as reported below.

**TABLE 2**

Endpoints	Biomarkers	Rationale	Expected Biomarker Outcome for Benefit	Benefit
Stratum Corneum Cohesiveness	Total Protein	More cohesiveness in healthy stratum corneum. Less cohesiveness in damaged skin.	↓	Strengthening stratum corneum  Improving skin barrier.
Differentiation	Keratin 1, 10 11	Higher differentiation in	↑	Improving skin health

		normal/healthy skin.		
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Total Protein Results: The results of the total protein from six consecutive tape strips as measured by SquameScan 850 were obtained. Referring to FIG. 12, comparative results according to the study are shown. The results showed improved cohesiveness at day 7.0, 14.0, and 22.0 measurement points vs. water control.

Keratin 1, 10, 11 Results: The results of Keratin 1, 10, 11 were normalized to total soluble protein. Referring to FIG. 13, comparative results according to the study are shown. . A significant increase of normalized Keratin 1, 10 11 as compared to water control at day 7 (100% increase) was observed. The normalized Keratin 1, 10, 11 level is further increased to 150% vs. water at day 14 and 22. The data is consistent with literature reports that dry skin dry skin is a condition characterized by hyperproliferation and decreased differentiation. (See Engeke, Jensen, Ekanayake-Mudiyanselage and Proksch “Effects of xerosis and aging on epidermal proliferation and differentiation”, Br. J. Dermatology, 137: 219-225 (1997).)

However, this is the first reported instance wherein measurable improvement in total keratin has been shown in the context of use of a rinse-off personal care composition.

The above described Results indicate that the variable lipid body wash delivers significant improvements in all standard moisturization measures (dryness grades, corneometer hydration, and TEWL). For the first time in the rinse-off context, the results show significant improvement in skin elasticity as compared to the water treatment control. The total protein results further reveal significant improvement in stratum corneum cohesiveness. Taken together, these findings support the conclusion that the petrolatum depositing bodywash wherein hydrophobic benefit agent is delivered in varying amounts over a treatment cycle according various embodiments as described herein improves the overall condition of skin. Improvement indices for each of the measures described herein above are as follows:

	Inventive Example A vs. Water Control	<i>p value (base size n=50)</i>
a) Skin Elastic Extension (Ue) Improvement Index	16	<i>p=0.003</i>
b) Skin Elastic Recovery (Ur) Improvement Index	21	<i>p=0.0004</i>

c) Skin Elasticity (R7) Improvement Index	4	<i>p=0.05</i>
d) Stratum Corneum Cohesiveness Improvement Index	23	<i>p&lt;0.0001</i>
e) Keratin Improvement Index	172	<i>p&lt;0.0001</i>
f) Visual Dryness Improvement (Dryness Reduction at 3 hours after three weeks of product treatment)	1.5	<i>p&lt;0.0001</i>
g) Corneometer Improvement (Increase in Corneometer at 3 hours after three weeks of product treatment)	3.6	<i>p&lt;0.0001</i>
h) TEWL Improvement (TEWL reduction at 3 hours after three weeks of product treatment)	0.5	<i>P=0.016</i>

Calculation of Skin Elasticity Improvement Index and Stratum Corneum Cohesiveness Improvement Index

1) Calculation of Skin Elasticity Improvement Index

a) Elastic Extension (U<sub>e</sub>) Improvement Index is calculated as:

$$[(U_e)^P_{end} - (U_e)^c_{end}] / (U_e)^c_{end} * 100 - [(U_e)^P_{ini} - (U_e)^c_{ini}] / (U_e)^c_{ini} * 100$$

wherein

(U<sub>e</sub>)<sup>c</sup><sub>ini</sub> is the initial elastic extension parameter at the beginning of the water control leg;

(U<sub>e</sub>)<sup>P</sup><sub>ini</sub> is the initial elastic extension parameter at the beginning of the test product leg;

(U<sub>e</sub>)<sup>c</sup><sub>end</sub> is the final elastic extension parameter at the end of the water control leg;

(U<sub>e</sub>)<sup>P</sup><sub>end</sub> is the final elastic extension parameter at the end of the test product leg.

b) Elastic Recovery (U<sub>r</sub>) Improvement Index is calculated as:

$$[(U_r)^P_{end} - (U_r)^c_{end}] / (U_r)^c_{end} * 100 - [(U_r)^P_{ini} - (U_r)^c_{ini}] / (U_r)^c_{ini} * 100$$

wherein

(U<sub>r</sub>)<sup>c</sup><sub>ini</sub> is the initial elastic recovery parameter at the beginning of the water control leg;



$(U_r)^P_{ini}$  is the initial elastic recovery at the beginning of the test product leg;

$(U_r)^c_{end}$  is the final elastic recovery at the end of the water control leg;

$(U_r)^P_{end}$  is the final elastic recovery at the end of the test product leg.

c) Elasticity ( $R_7$ ) Improvement Index is calculated as:

$$[(R_7)^P_{end} - (R_7)^c_{end}] / (R_7)^c_{end} * 100 - [(R_7)^P_{ini} - (R_7)^c_{ini}] / (R_7)^c_{ini} * 100$$

wherein

$(R_7)^c_{ini}$  is the initial elasticity at the beginning of the water control leg;

$(R_7)^P_{ini}$  is the initial elasticity at the beginning of the test product leg;

$(R_7)^c_{end}$  is the final elasticity at the end of the water control leg;

$(R_7)^P_{end}$  is the final elasticity at the end of the test product leg.

## 2) Calculation of Stratum Corneum Cohesiveness Improvement Index

a) Stratum Corneum Cohesiveness Improvement Index is calculated as:

$$[(Protein)^c_{end} - (Protein)^P_{end}] / (Protein)^c_{end} * 100 - [(Protein)^c_{ini} - (Protein)^P_{ini}] / (Protein)^c_{ini} * 100 \quad \text{wherein}$$

$(Protein)^c_{ini}$  is the sum of initial protein absorption of tape 1 to tape 6 at the beginning of the water control leg;

$(Protein)^P_{ini}$  is the sum of initial protein absorption of tape 1 to tape 6 at the beginning of the test product leg;

$(Protein)^c_{end}$  is the sum of final protein absorption of tape 1 to tape 6 at the end of the water control leg;

$(Protein)^P_{end}$  is the sum of final protein absorption of tape 1 to tape 6 at the end of the test product leg.

## 3) Calculation of Keratin 1, 10, 11 Improvement Index

Keratin 1, 10, 11 Improvement Index is calculated as:

$$[(Keratin)^c_{end} - (Keratin)^P_{end}] / (Keratin)^c_{end} * 100 - [(Keratin)^c_{ini} - (Keratin)^P_{ini}] / (Keratin)^c_{ini} * 100 \quad \text{wherein}$$

$(Keratin)^c_{ini}$  is the initial Keratin 1, 10, 11 normalized to total soluble protein at the beginning of the water control leg;

$(Keratin)^P_{ini}$  is the initial Keratin 1, 10, 11 normalized to total soluble protein at the beginning of the test product leg;

$(Keratin)^c_{end}$  is the final Keratin 1, 10, 11 normalized to total soluble protein at the end of the water control leg;

(Keratin)<sup>P</sup><sub>end</sub> is the final Keratin 1, 10, 11 normalized to total soluble protein at end of the test product leg.

**Table 3: Results of Inventive Composition Example A vs. Water Control**

	Inventive Example A	<i>p value</i> (base size n=50)
a) Skin Elastic Extension (Ue) Improvement Index	16	<i>p=0.003</i>
b) Skin Elastic Recovery (Ur) Improvement Index	21	<i>p=0.0004</i>
c) Skin Elasticity (R7) Improvement Index	4	<i>p=0.05</i>
d) Stratum Corneum Cohesiveness Improvement Index	23	<i>p&lt;0.0001</i>
e) Keratin Improvement Index	172	<i>p&lt;0.0001</i>

#### IV. Personal Care Articles And Personal Care Compositions

The present disclosure contemplates use of personal care compositions and articles comprising personal care compositions. In some embodiments, personal care articles for dispensing a personal care compositions comprises a single chamber package and a personal care article. It will be appreciated that other embodiments of personal care articles and personal care compositions are contemplated for use according to the disclosure herein, and the following descriptions regarding possible embodiments is non-limiting.

Single chamber package comprises a dispensing orifice, a first zone proximal to the dispensing orifice, a second zone medial to the dispensing orifice, and a third zone distal to the dispensing orifice. The personal care article comprises a first personal care composition, a second personal care composition and a third personal care composition. The first personal care composition is substantially within the first zone and comprises a first concentration of a hydrophobic benefit material. The second personal care composition is substantially within the second zone and comprises a second concentration of a hydrophobic benefit material. The third personal care composition is substantially within the third zone and comprises a third concentration of a hydrophobic benefit material. The second concentration is greater than the first concentration and the third concentration of the hydrophobic benefit material. The first personal care composition is capable of being substantially dispensed prior to the second personal care composition and the third personal care composition. The second

personal care composition is capable of being substantially dispensed prior to the third personal care composition.

The personal care article used in accordance with the present disclosure, in most embodiments, is statically stable. In most embodiments, the personal care article used in accordance with the present disclosure is dynamically stable according to the Dynamic Stability Shipping Method disclosed in the Test Methods below.

In some embodiments, the first personal care composition is in physical contact with the second personal care composition within the single chamber package. The second personal care composition, in another embodiment, is in physical contact with the third personal care composition within the single chamber package.

In one embodiment, the first zone, second zone and/or third zone as disclosed herein comprises from about 10% to about 70%, by volume, of the package. The first zone, second zone and/or third zone as disclosed herein comprise from about 10% to about 60%, from about 10% to about 50%, from about 10% to about 40%, from about 10% to about 30%, from about 10% to about 20%, by volume, of the package. In other embodiments, the first zone, second zone and/or third zone as disclosed herein comprises from about 20% to about 70%, from about 20% to about 60%, from about 20% to about 50%, from about 20% to about 40%, from about 20% to about 30%, by volume, of the package. In other embodiments, the first second and/or third zone as disclosed herein comprises from about 30% to about 70%, from about 30% to about 60%, from about 30% to about 50%, from about 30% to about 40%, by volume, of the package.

The personal care article used in accordance with the present disclosure comprises a single chamber package can contain any number or zones and compositions, such as for example, four zones and four compositions, five zones and five compositions, six zones and six compositions, twelve zones and twelve compositions, and so on. Each of these compositions is capable of substantially dispensing prior to the composition before it in a substantially sequential manner. For example, the fourth personal care composition substantially within the fourth zone is capable of dispensing prior to the fifth personal care composition within the fifth zone, etc. In some embodiments, a dual-chamber delivery article having side-by-side chambers with a control valve or cap to regulate dispensing from each chamber may be used. In other embodiments, a dual-chamber delivery article with end-to-end chambers may be selected, where product is dispensed separately from each chamber. In

yet other embodiments, a kit of two or more separate bottles that may nest or stack or otherwise inter-fit may be used for dispensing the personal care compositions.

The personal care article used in accordance with the present disclosure is filled to comprise a headspace. In some embodiments, the personal care article used in accordance with the present disclosure comprises a headspace that is less than 10%, is less than 6%, less than 5% and less than 4%. In other embodiments, the personal care article used in accordance with the present disclosure comprises a headspace that is less than 3%, less than 2% and less than 1%.

In another aspect, each personal care composition comprises a dye, colorant or the like, such that each personal care composition is a distinct color or hue. For example, the first personal care composition is a yellow color, the second personal care composition is an orange color and the third personal care composition is a purple color.

The amount or concentration of hydrophobic benefit materials in the first personal care composition, second personal care composition and third personal care composition are usually formulated, by weight of the composition, at less than about 75%, less than about 65%, less than about 60%, less than about 60%, less than about 55%, less than about 50%, less than about 45%, less than about 40%, less than about 35%, less than about 30%, less than about 25%, less than about 20%, less than about 10%, less than about 5%, less than about 4%, less than about 3%, less than about 2%, less than about 1%. The first personal care composition, second personal care composition and third personal care composition comprises from about 1.0% to about 60%, from about 5% to about 60%, from about 10% to about 50%, from about 20% to about 45%, by weight of the personal care composition, of a hydrophobic benefit material.

In some embodiments, the first concentration can comprise from about 10% to less than about 50% or, from about 10% to about 40%, by weight of the first personal care composition. The first concentration of hydrophobic material, in other embodiments, comprise from about 15% to less than 45% or 15% to less than 35% by weight of the first personal care composition, of hydrophobic benefit material. The first concentration, in some embodiments, comprise from about 20% to about 40% and from about 25% to about 40%, by weight of the first personal care composition.

In some embodiments, the second concentration comprises from greater than 30% to about 70%, greater than about 35% to about 65%, by weight of the second personal care composition, of hydrophobic benefit material. In other embodiments, the second concentration comprises from about 40 to about 60% and about 55% by weight of the second personal care composition.

In some embodiments, the third concentration can comprise from about 10% to less than about 50% or, from about 10% to about 40%, by weight of the third personal care composition. The third concentration of hydrophobic material, in other embodiments, comprise from about 15% to less than 45% or 15% to less than 35% by weight of the third personal care composition, of hydrophobic benefit material. The third concentration, in some embodiments, comprise from about 20% to about 40% and from about 25% to about 40%, by weight of the third personal care composition.

In one embodiment, the first personal care composition, second personal care composition and third personal care composition used in accordance with the present disclosure are multi-phase compositions and comprise one or more phases or one or more of the components described in the phases below:

The personal care compositions used in accordance with the present disclosure comprise a benefit phase or benefit phase components. The benefit phase in the present disclosure, in most embodiments, is anhydrous and is substantially free of water. In some embodiments, the benefit phase is substantially free or free of surfactant.

Hydrophobic benefit materials suitable for use in the present disclosure typically have a Vaughan Solubility Parameter of from about 5 (cal/cm<sup>3</sup>)<sup>1/2</sup> to about 15 (cal/cm<sup>3</sup>)<sup>1/2</sup>, as defined by Vaughan in Cosmetics and Toiletries, Vol. 103. The Vaughan Solubility Parameter (VSP) as used herein is a parameter used to define the solubility of hydrophobic materials. Vaughan Solubility parameters are well known in the various chemical and formulation arts and typically have a range of from 5 to 25. Non-limiting examples of hydrophobic benefit materials having VSP values ranging from about 5 to about 15 include the following: Cyclomethicone 5.92, Squalene 6.03, Petrolatum 7.33, Isopropyl Palmitate 7.78, Isopropyl Myristate 8.02, Castor Oil 8.90, Cholesterol 9.55, as reported in Solubility, Effects in Product, Package, Penetration and Preservation, C. D. Vaughan, Cosmetics and Toiletries, Vol. 103, October 1988.

The hydrophobic benefit materials for use in the benefit phase of the composition have, in some embodiments, a rheology profile as defined by Consistency value (k) and Shear Index (n). The term "Consistency value" or "k" as used herein is a measure of lipid viscosity and is used in combination with Shear Index, to define viscosity for materials whose viscosity is a function of shear. The measurements are made at 35°C and the units are poise (equal to 100 cps). The term "Shear Index" or "n" as used herein is a measure of lipid viscosity and is used in combination with Consistency value, to define viscosity for materials whose viscosity is a function of shear. The measurements are made at 35°C and the units are dimensionless. Consistency value (k) and Shear Index (n) are more fully described in the Test Methods below. In accordance with some embodiments, Consistency value ranges are 1-10,000 poise (1/sec)<sup>n-1</sup>, typically 10-2000 poise (1/sec)<sup>n-1</sup> and more typically 50-1000 poise (1/sec)<sup>n-1</sup>. Shear Index ranges are 0.1-0.8, typically 0.1-0.5 and more typically 0.20-0.4. These embodiments having the described rheological properties are especially useful in providing the personal cleansing compositions with improved deposition of benefit agents on skin.

In one embodiment, the benefit phase is comprised of the hydrophobic benefit materials selected from the group consisting of petrolatum, lanolin, derivatives of lanolin (e.g. lanolin oil, isopropyl lanolate, acetylated lanolin, acetylated lanolin alcohols, lanolin alcohol linoleate, lanolin alcohol riconoleate) hydrocarbon oils (e.g. mineral oil) natural and synthetic waxes (e.g. micro-crystalline waxes, paraffins, ozokerite, lanolin wax, lanolin alcohols, lanolin fatty acids, polyethylene, polybutene, polydecene, pentahydrosqualene) volatile or non-volatile organosiloxanes and their derivatives (e.g. dimethicones, cyclomethicones, alkyl siloxanes, polymethylsiloxanes, methylphenylpolysiloxanes), natural and synthetic triglycerides (e.g. castor oil, soy bean oil, sunflower seed oil, maleated soy bean oil, safflower oil, cotton seed oil, corn oil, walnut oil, peanut oil, olive oil, cod liver oil, almond oil, avocado oil, palm oil, sesame oil) and combinations thereof. In one aspect, at least about 50% by weight of the hydrophobic benefit materials are selected from the groups of petrolatum, mineral oil, paraffins, polyethylene, polybutene, polydecene, dimethicones, alkyl siloxanes, cyclomethicones, lanolin, lanolin oil, lanolin wax. In one embodiment, the remainder of the hydrophobic benefit material is selected from: isopropyl palmitate, cetyl riconoleate, octyl isononanoate, octyl palmitate, isocetyl stearate, hydroxylated milk glyceride and combinations thereof. The benefit phase of the personal care composition, in some embodiments, comprises a combination of petrolatum and mineral oil.

In some embodiments, the personal care composition used in accordance with the present disclosure comprises a surfactant phase. The personal care composition typically comprises from about 1 % to about 100 %, by weight of the composition; from about 5% to about 85%; by weight of the composition, from about 10% to 80%, by weight of the composition; from about 20 to 70%, by weight of the composition; from about 25% to 60%, by weight of the composition, from about 30% to about 50%, by weight of the composition, of a surfactant phase.

In some embodiments, the surfactant phase comprises a structured domain that is comprised of a mixture of surfactants. The presence of structured domain enables the incorporation of high levels of hydrophobic benefit materials in a separate phase which is not emulsified within composition. In one aspect, the structured domain in the composition is characterized as, or is, an opaque structured domain. In one aspect, the opaque structured domain is characterized as, or is, a lamellar phase. The lamellar phase produces a lamellar gel network. The lamellar phase provides resistance to shear, adequate yield to suspend particles and droplets and at the same time provides long term stability, since it is thermodynamically stable. The lamellar phase tends to have a higher viscosity thus minimizing the need for viscosity modifiers.

In one aspect, the surfactant phase comprises a domain that is comprised of a mixture of surfactants and is a micellar phase. A micellar phase is optically isotropic. Micelles are approximately spherical in shape. Other shapes such as ellipsoids, cylinders, and bilayers are also possible. In one aspect, the micellar phase is structured to enhance viscosity and to suspend particles. This can be accomplished using viscosity modifiers such as those defined below as water structurants.

In some embodiments, the surfactant phase comprises a surfactant component which comprises of a mixture of surfactants including lathering surfactants or a mixture of lathering surfactants. The surfactant phase comprises surfactants suitable for application to the mammalian skin or hair and is compatible with water and the other ingredients of the composition used in accordance with the present disclosure. These surfactants include anionic, nonionic, cationic, zwitterionic, amphoteric, soap, or combinations thereof. Typically, anionic surfactant comprises at least 40% of the surfactant component. The personal care composition, in some embodiments, comprises the surfactant component at concentrations ranging from about 2% to about 40%, from about 4% to about 25%, about 1% to about 21%, about 3 to 15%, by weight of the composition, of the surfactant component.

Suitable surfactants are described in McCutcheon's, Detergents and Emulsifiers, North American edition (1986), published by Allured Publishing Corporation; and McCutcheon's, Functional Materials, North American Edition (1992); and in U.S. Pat. No. 3,929,678 issued to Laughlin, et al on December 30, 1975.

In accordance with some embodiments, linear anionic surfactants for use in the surfactant phase of the personal care composition include ammonium lauryl sulfate, ammonium laureth sulfate, sodium lauryl sulfate, sodium laureth sulfate, potassium laureth sulfate, sodium lauryl sarcosinate, sodium lauroyl sarcosinate, lauryl sarcosine, cocoyl sarcosine, ammonium cocoyl sulfate, potassium lauryl sulfate, and combinations thereof.

Branched anionic surfactants and monomethyl branched anionic surfactants suitable for the present disclosure are described in a commonly owned U.S. Publication No. 60/680,149 entitled "Structured Multi-phased Personal Cleansing Compositions Comprising Branched Anionic Surfactants" filed on May 12, 2005 by Smith, et al. Branched anionic surfactants include but are not limited to the following surfactants: sodium trideceth sulfate, sodium tridecyl sulfate, sodium C<sub>12-13</sub> alkyl sulfate, and C<sub>12-13</sub> pareth sulfate and sodium C<sub>12-13</sub> pareth-*n* sulfate.

In one aspect of the personal care compositions used in accordance with the present disclosure comprise an amphoteric surfactant, a zwitterionic surfactant and combinations thereof. In one embodiment, the personal care composition comprises at least one amphoteric surfactant. Amphoteric surfactant suitable for use in the present disclosure include those that are broadly described as derivatives of aliphatic secondary and tertiary amines in which the aliphatic radical can be straight or branched chain and wherein one of the aliphatic substituents contains from about 8 to about 18 carbon atoms and one contains an anionic water solubilizing group, e.g., carboxy, sulfonate, sulfate, phosphate, or phosphonate. Examples of compounds falling within this definition are sodium 3-dodecyl-aminopropionate, sodium 3-dodecylaminopropane sulfonate, sodium lauryl sarcosinate, N-alkyltaurines such as the one prepared by reacting dodecylamine with sodium isethionate according to the teaching of U.S. Pat. No. 2,658,072, N-higher alkyl aspartic acids such as those produced according to the teaching of U.S. Pat. No. 2,438,091, and the products described in U.S. Pat. No. 2,528,378. In one aspect, the personal care composition comprises an amphoteric surfactant that is selected from the group consisting of sodium lauroamphoacetate, sodium cocoamphoacetate, disodium lauroamphoacetate disodium cocodiamphoacetate, and



combinations thereof. Moreover, Amphoacetates and diamphoacetates are also used in some embodiments as disclosed herein.

Zwitterionic surfactants suitable for use include those that are broadly described as derivatives of aliphatic quaternary ammonium, phosphonium, and sulfonium compounds, in which the aliphatic radicals can be straight or branched chain, and wherein one of the aliphatic substituents contains from about 8 to about 18 carbon atoms and one contains an anionic group, e.g., carboxy, sulfonate, sulfate, phosphate, or phosphonate. Zwitterionic surfactants suitable for use in the personal care composition include alkyl betaines, including cocoamidopropyl betaine.

The personal care composition used in accordance with the present disclosure is typically free of alkyl amines and alkanolamide to ensure mildness of the composition to the skin.

An electrolyte can be added per se to the personal care composition or it can be formed in situ via the counterions included in one of the raw materials. The electrolyte typically includes an anion comprising phosphate, chloride, sulfate or citrate and a cation comprising sodium, ammonium, potassium, magnesium or combinations thereof. In accordance with some embodiments, electrolytes are sodium chloride, ammonium chloride, sodium or ammonium sulfate. The electrolyte is typically added to the surfactant phase of the composition in the amount of from about 0.1% to about 6%; from about 1% to about 5%, more typically from about 2% to about 4%, more typically from about 3% to about 4%, by weight of the personal care composition.

In one embodiment, the first personal care composition comprise a first concentration of surfactant, the second personal care composition comprises a second concentration of surfactant and the third personal care composition comprises a third concentration of surfactant. The first concentration of surfactant is different from the second concentration of surfactant and the third concentration of surfactant, in some embodiments. In one aspect, the first personal care composition has a first concentration of surfactant that is a greater than the second concentration of surfactant in the second personal care compositions and is the same as or greater than the third concentration of surfactant in the third personal care compositions. In one aspect, the first personal care composition has a lower concentration of surfactant than the second and the third personal care compositions.

In some embodiments, the personal care compositions used in accordance with the present disclosure comprise a structured aqueous phase. The structured aqueous phase, in one

embodiment, comprises a water structurant and water. The structured aqueous phase has a pH in the range from about 5 to about 9.5, or in one aspect have a pH of about 7. In one embodiment, the structured aqueous phase is hydrophilic. In one aspect, the structured aqueous phase is a hydrophilic, non-lathering gelled water phase.

In some embodiments, the structured aqueous phase comprises less than about 5%, less than about 3%, less than about 1%, by weight of the structured aqueous phase, of a surfactant component. In one aspect, the structured aqueous phase is free of lathering surfactants in the composition. In one embodiment, the structured aqueous phase as disclosed herein comprises from about 30% to about 99%, more than about 50%, more than about 60%, more than about 70%, more than about 80%, by weight of the structured aqueous phase, of water.

In one embodiment, the structured aqueous phase comprises a water structurant. The water structurant is selected from the group consisting of inorganic water structurants (e.g. silicas, polyacrylates, polyacrylamides, modified starches, crosslinked polymeric gellants, copolymers) charged polymeric water structurants (e.g. Acrylates/Vinyl Isodecanoate Crosspolymer available, STABYLEN 30® available from 3V SIGMA S.P.A of Bergamo Italy), Acrylates/C10-30 Alkyl Acrylate Crosspolymer (e.g. PEMULEN™ TR1 and TR2 polymers available from NOVEON®), Carbomers, Ammonium Acryloyldimethyltaurate/VP Copolymer (e.g. Aristoflex® AVC available from Clariant), Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer (e.g. ARISTOFLEX® HMB available from Clariant), Acrylates/Ceteth-20 Itaconate Copolymer (e.g. STRUCTURE® 3001 available from National Starch), Polyacrylamide (e.g. SEPIGEL™ 305 available from SEPPIC), water soluble polymeric structurants (e.g. cellulose gums and gel, and starches), associative water structurants (e.g. xanthum gum, gellum gum, pectins, alginates such as propylene glycol alginate), and combinations thereof. In some embodiments, the structured aqueous phase comprises from about 0.1% to about 30%, from about 0.5% to about 20%, from about 0.5% to about 10%, and from about 0.5% to about 5%, by weight of the structured aqueous phase, of a water structurant. In some embodiments, a water structurant for the structured aqueous phase has a net cationic charge, net anionic charge, or neutral charge.

While not essential for the purposes as disclosed herein, the non-limiting list of optional materials, illustrated hereinafter are suitable for use in personal care compositions,

and may be incorporated in certain embodiments, for example to assist or enhance cleansing performance, for treatment of the skin, or to modify the aesthetics of the personal care composition. Optional materials useful in the products herein are described by their cosmetic and/or therapeutic benefit or their postulated mode of action or function. These descriptions are non-limiting and made for the sake of convenience because it is understood that these materials can provide more than one benefit, function or operate via more than one mode of action. The precise nature of these optional materials, and levels of incorporation thereof, will depend on the physical form of the composition and the nature of the cleansing operation for which it is to be used. The amount of optional materials in compositions are usually formulated, by weight of the composition, at less than about less than about 6%, less than about 5%, less than about 4%, less than about 3%, less than about 2%, less than about 1%, less than about 0.5%, less than about 0.25%, less than about 0.1%, less than about 0.01%, less than about 0.005%.

In some embodiments as disclosed herein, comprise optional ingredients, which are selected from the group consisting of thickening agents, low density microspheres (e.g. EXPANCEL® microspheres available from 091 WE40 d24, Akzo Nobel and others described in commonly owned and assigned U.S. Patent Publication No. 2004/0092415A1 published on May 13, 2004), preservatives, antimicrobials, fragrances, chelators (e.g. such as those described in U.S. Pat. No. 5,487,884 issued to Bisset et al.), sequestrants, vitamins (e.g. Retinol), vitamin derivatives (e.g. tocophenyl acetate, niacinamide, panthenol), sunscreens, desquamation actives (e.g. such as those described in U.S. Pat. No. 5,681,852 and 5,652,228 issued to Bisset), anti-wrinkle/ anti-atrophy actives (e.g. N-acetyl derivatives, thiols, hydroxyl acids, phenol), anti-oxidants (e.g. ascorbic acid derivatives, tocophenol), skin soothing agents/skin healing agents (e.g. panthenoic acid derivatives, aloe vera, allantoin), skin lightening agents (e.g. kojic acid, arbutin, ascorbic acid derivatives), skin tanning agents (e.g. dihydroxyacetone), polymeric phase structurant (e.g. naturally derived polymers, synthetic polymers, crosslinked polymers, block copolymers, copolymers, hydrophilic polymers, nonionic polymers, anionic polymers, hydrophobic polymers, hydrophobically modified polymers, associative polymers, and oligomers); a liquid crystalline phase inducing structurant (e.g. trihydroxystearin available from Rheox, Inc. under the trade name THIXCIN® R), organic cationic deposition polymer (e.g. Polyquaternium 10 available from Amerchol Corp., guar hydroxypropyltrimonium chloride available as JAGUAR® C-17 from Rhodia Inc., and N-HANCE® polymer series commercially available from AQUALON), pH

regulators (e.g. triethanolamine), anti-acne medicaments, essential oils, sensates, pigments, colorants, pearlescent agents, interference pigments (e.g. such as those disclosed in U.S. Pat. No. 6,395,691 issued to Liang Sheng Tsaur, U.S. Pat. No. 6,645,511 issued to Aronson et al., U.S. Pat. No. 6,759,376 issued to Zhang et al., U.S. Pat. No. 6,780,826 issued to Zhang et al.) particles (e.g. talc, kolin, mica, smectite clay, cellulose powder, polysiloxane, silicas, carbonates, titanium dioxide, polyethylene beads) hydrophobically modified non-platelet particles (e.g. hydrophobically modified titanium dioxide and other materials described in a commonly owned, patent application published on Aug. 17, 2006 under Publication No. 2006/0182699A by Taylor, et al.) and combinations thereof. Other optional ingredients are most typically those materials approved for use in cosmetics and that are described in the CTFA Cosmetic Ingredient Handbook, Second Edition, The Cosmetic, Toiletries, and Fragrance Association, Inc. 1988, 1992.

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#### V. Methods Related To Personal Care Articles And Personal Care Compositions

##### Measuring Lather Volume

Lather volume of a personal skin care composition can be measured using a graduated cylinder and a tumbling apparatus. A 1,000 ml graduated cylinder is chosen which is marked in 10 ml increments and has a height of 14.5 inches at the 1,000 ml mark from the inside of its base (for example, Pyrex No. 2982). Distilled water (100 grams at 23° C.) is added to the graduated cylinder. The cylinder is clamped in a rotating device which clamps the cylinder with an axis of rotation that transects the center of the graduated cylinder. One gram of the total personal cleansing composition with specified cleansing phase to benefit phase ratio (0.75 g of the cleansing phase and 0.25 g of the benefit phase, or 0.45g of the cleansing phase and 0.55 g of the benefit phase) is added into the graduated cylinder and the cylinder is capped. The cylinder is rotated at a rate of 10 revolutions in about 20 seconds, and stopped in a vertical position to complete the first rotation sequence. A timer is set to allow 30 seconds for the lather thus generated to drain. After 30 seconds of such drainage, the first lather volume is measured to the nearest 10 ml mark by recording the lather height in ml up from the base (including any water that has drained to the bottom on top of which the lather is floating).

If the top surface of the lather is uneven, the lowest height at which it is possible to see halfway across the graduated cylinder is the first lather volume (ml). If the lather is so coarse that a single or only a few foam cells (“bubbles”) reach across the entire cylinder, the height at which at least 10 foam cells are required to fill the space is the first lather volume, also in ml up from the base. Foam cells larger than one inch in any dimension, no matter where they occur, are designated as unfilled air instead of lather. Foam that collects on the top of the graduated cylinder but does not drain is also incorporated in the measurement if the foam on the top is in its own continuous layer, by adding the ml of foam collected there using a ruler to measure thickness of the layer, to the ml of foam measured up from the base. The maximum foam height is 1,000 ml (even if the total foam height exceeds the 1,000 ml mark on the graduated cylinder). One minute after the first rotation is completed, a second rotation sequence is commenced which is identical in speed and duration to the first rotation sequence. The second lather volume is recorded in the same manner as the first, after the same 30 seconds of drainage time. A third sequence is completed and the third lather volume is measured in the same manner, with the same pause between each for drainage and taking the measurement.

The lather result after each sequence is added together and the Total Lather Volume determined as the sum of the three measurements, in ml. The Flash Lather Volume is the result after the first rotation sequence only, in ml, i.e., the first lather volume. Compositions according to the present disclosure perform significantly better in this test than similar compositions in conventional emulsion form.

#### Microcentrifugation Method:

The Microcentrifugation Method determines the variation of the percent of hydrophobic benefit material per dose in a package that comprises a personal care article. As an overview, the personal care articles being tested are dispensed in 10.0 mL sample sizes and these samples are centrifuged. Centrifugation separates the sample size of personal care articles into distinguishable layers. The first personal care composition, second personal care composition and third personal care composition have multiple distinguishable layers, for example a microsphere layer, a surfactant layer, and a benefit layer that comprises hydrophobic benefit material, as shown in FIG. 15B and FIG. 15C. After centrifugation, the volume percentage of the benefit phase for each sample is determined and plotted per dose of

personal care article to obtain the hydrophobic benefit material distribution profile of the personal care article throughout the product package.

Table 4: Description of Apparatus used in the Microcentrifugation Method	
Apparatus:	Description:
Micro-centrifuge	VWR Galaxy 16DH
2mL Micro-centrifuge clear tubes	VWR cat. No. 20170-170
Disposable syringes	1mL, VWR cat. No. BD309602
Top Load balance	Capable of weighing to 2 decimal cases.
Clear plastic cups	207mL Solo Plastic cup
Centrifuge tube stand	capacity to hold at least 24 tubes
Electronic Digital Caliper	capable of measuring 2 decimal cases in mm

To prepare the samples for a 295mL package of a personal care article, label 24 clear plastic cups 1-24. Place cup 1 on top of balance and tare. Open package containing the personal care article, dispense  $8.80 \text{ g} \pm 0.50\text{g}$  of product in cup 1, and record the weight of each sample. Repeat these instructions for all 24 cups, or for as many doses you can get from one package. If composition gets stuck in the package, tap the package in descending motion for four times.

Next, label 24 centrifuge tubes 1-24 doses. Then, mix the sample in cup 1 well by stirring the sample with a stirrer by hand and then draw the sample into a syringe. Insert the syringe all the way to the bottom of the centrifuge tube. Slowly push the plunger as you withdraw the syringe from the centrifuge tube, making sure no air bubbles or gaps are formed. Check for air bubbles, if any air bubble is found tap the centrifuge tube until sample fills the gaps left by the air bubbles. Load the syringe with more sample of the product and bring the extremity of the syringe to the top of the sample of the product that is inside the centrifuge tube. Slowly push the plunger while withdrawing the syringe from the centrifuge tube. Check for air bubbles, and eliminate them by tapping down the centrifuge tube. Fill the centrifuge tube to its maximum capacity with the sample of the product (i.e. all the way to the rim), cap the centrifuge tube and place in the centrifuge tube rack. Repeat these steps until all 24 centrifuge tubes are filled.

Load the centrifuge as described in the manufacturer's instrument operation section of the instruction manual. Centrifuge each of the samples for 15 minutes at 13,000 rpm. Once

centrifugation is done, remove each centrifuge tube from centrifuge. Next, use a caliper to measure the length of benefit phase to 1/100 of mm. Record the length of benefit phase for each sample.

FIG. 15A is a diagram of the layers of a personal care composition after centrifugation. FIG. 15B and FIG. 15C are photographs that exemplify the measurement of the benefit phase comprising hydrophobic benefit material within in the centrifuged samples.

The volume of each dispensed sample is calculated by convert the weight of each sample to volume using product density (0.88 g/mL).

$$\text{Volume}_{(\text{sample})} = \frac{\text{Weight}}{\text{Density}}$$

The total volume dispensed is calculated by adding the volume of a sample to the sum of the volumes of all previous samples. The percent hydrophobic benefit material is calculated using equation of calibration curve, below. In this equation, y = length of benefit layer and x = the percentage hydrophobic benefit material in the sample.

$$X = \frac{y + 3.0416}{0.3867}$$

FIG. 16 depicts a calibration curve that was generated from 20 to 70% concentration of hydrophobic benefit material. This curve was used to transform mm of hydrophobic benefit material to percent of hydrophobic benefit material in the composition.

Finally, plot the percentage of hydrophobic benefit material versus the total volume dispensed to obtain the hydrophobic benefit material distribution profile of the personal care article throughout the package.

#### Magnetic Resonance Imaging (MRI) Method:

The MRI Method is used to obtain images and quantitatively describe the benefit distribution in 3-Dimension. The Instrument used is a 4.7T Magnex Scientific magnet with a 60 cm horizontal bore. The data is collected using a Bruker 25 cm imaging coil and Bruker Paravision 3.0.2. The data is collected using a spin-echo pulse sequence, repetition time of 1000 ms and echo time of 15 ms. Images were acquired of 32 of 2mm thick slices were acquired along the flat surface of the package or bottle. The fields of view were 22 cm x 10 cm with data size of 256 x 128, which results in in-plane pixel resolutions of 86 um x 78 um.

The customized imaging analysis software used to analyze the MRI images is a Matlab based graphical user interface program, hereinafter referred to as "GUI program". This GUI program was developed in order to quantitatively describe benefit layer distribution in 3-dimensions. The GUI program sets thresholds based on MRI intensity to segment background and/or void region, benefit region and surfactant region. The distribution of hydrophobic benefit material along the height and radial are summed and plotted as FIG. 7 and FIG. 18. FIG. 17 illustrates GUI based analysis of personal care composition phase distribution along the radial dimensions of the package. FIG. 18 illustrates GUI based analysis of personal care composition phase distribution along the height of the package.

#### Dynamic Shipping Stability Method:

The dynamic shipping stability method is a simulated shipping test that is conducted to illustrate the impact of the amount headspace on the distribution profile of hydrophobic benefit material in a personal care article used in accordance with the present disclosure. The method is conducted on a vibration table, such as a MTS Vibration Table, available from Lansmont TTV of Monterrey, California.

The method tests shipping cases of personal care articles. There are 6 personal care articles or packages that are comprised within a shipping case. The personal care articles are filled with inventive example B using inventive filler profile B with various headspaces at 16%, 10% and 3%, of the volume of the personal care article, respectively. The shipping cases are submitted to simulated shipping conditions. The temperature of the shipping cases of personal care articles can be varied to simulate shipping conditions from cold to warm climate regions.

Prior to submitting the shipping cases to simulated shipping conditions, MRI images of each personal care article are obtained by the MRI method at 25°C. Next, the shipping cases are subjected to simulated shipping conditions

There are four steps to induce the simulated shipping conditions:

Step 1: The shipping cases are dropped once at each of the six orientations for a total of six times. The "six orientations," of the shipping cases used are up, down, and on each of the four sides.

Step 2: The ASTM D4169 Truck Level 2 method is performed on the shipping cases in upright positions for three hours.



Step 3: The ASTM D4728 Truck method is performed with shipping cases at the six orientations for thirty minutes for each orientation.

Step 4: The shipping cases are dropped once at each of the six orientations for a total of six times.

After submitting the shipping cases to simulated shipping conditions, MRI images are taken for each personal care article by the MRI method at 25°C.

The MRI images prior to and after simulated shipping conditions are visually compared and graded of the shipping stability. The MRI images are compared on the amount of phase mixing, the presence of a zone of high concentration of hydrophobic benefit material, the orientation of the concentration of hydrophobic benefit material medial to the dispensing orifice, the amount of void volume and an orientation of the void volume at the end proximal to the dispensing orifice. If after submitting the shipping cases to simulated shipping conditions, the MRI images that show an excessive amount of mixing, the absence of a zone of high concentration of hydrophobic benefit material, an excessive amount of void volume and/or the volume is located medial or distal to the dispensing orifice; the personal care article would fail the dynamic stability shipping method. Conversely, if after submitting the shipping cases to simulated shipping conditions, the MRI images that show only a slight amount of mixing, the presence of a zone of high concentration of hydrophobic benefit material which is located medial to the dispensing orifice, a small amount of void volume located proximal to the dispensing orifice; the personal care article would pass the dynamic stability shipping method.

The results of the dynamic shipping stability method are shown below in FIG. 19A, FIG. 19B and FIG. 19C. As shown in FIG. 19A, the packages with 16% headspace shows extensive co-mixing of the two phases and thus, failed the shipping dynamic shipping stability method. As shown in FIG. 19B, the packages with 10% headspace shows improved dynamic shipping stability method as the zone of high concentration of hydrophobic benefit material is still apparent in the MRI image. As shown in FIG. 19C, the packages with 3% headspace shows the best shipping stability as the variable concentrations of hydrophobic benefit material is maintained after shipping protocol.

Ultracentrifugation Method:

The Ultracentrifugation Method is used to determine the percent of a structured domain or an opaque structured domain that is present in a personal care composition that comprises a surfactant phase or a surfactant component. The method involves the separation of a composition by ultracentrifugation into separate but distinguishable layers. The first personal care composition, second personal care composition and third personal care composition have multiple distinguishable layers, for example a non-structured surfactant layer, a structured surfactant layer, and a benefit layer.

First, dispense about 4 grams of personal care composition into Beckman Centrifuge Tube (11x60mm). Next, place the centrifuge tubes in an Ultracentrifuge (Beckman Model L8-M or equivalent) and ultracentrifuge using the following conditions: 50,000rpm, 18 hours, and 25°C.

After ultracentrifuging for 18 hours, determine the relative phase volume by measuring the height of each layer visually using an Electronic Digital Caliper (within 0.01mm). First, the total height is measured as  $H_a$  which includes all materials in the ultracentrifuge tube. Second, the height of the benefit layer is measured as  $H_b$ . Third, the structured surfactant layer is measured as  $H_c$ . The benefit layer is determined by its low moisture content (less than 10% water as measured by Karl Fischer Titration). It generally presents at the top of the centrifuge tube. The total surfactant layer height ( $H_s$ ) can be calculated by this equation:

$$H_s = H_a - H_b$$

The structured surfactant layer components may comprise several layers or a single layer. Upon ultracentrifugation, there is generally an isotropic layer at the bottom or next to the bottom of the ultracentrifuge tube. This clear isotropic layer typically represents the non-structured micellar surfactant layer. The layers above the isotropic phase generally comprise higher surfactant concentration with higher ordered structures (such as liquid crystals). These structured layers are sometimes opaque to naked eyes, or translucent, or clear. There is generally a distinct phase boundary between the structured layer and the non-structured isotropic layer. The physical nature of the structured surfactant layers can be determined through microscopy under polarized light. The structured surfactant layers typically exhibit distinctive texture under polarized light. Another method for characterizing the structured surfactant layer is to use X-ray diffraction technique. Structured surfactant layer display multiple lines that are often associated primarily with the long spacings of the liquid crystal

structure. There may be several structured layers present, so that  $H_c$  is the sum of the individual structured layers. If a coacervate phase or any type of polymer-surfactant phase is present, it is considered a structured phase.

Finally, the structured domain volume ratio is calculated as follows:

$$\text{Structured Domain Volume Ratio} = H_c / H_s * 100\%$$

If there is no benefit phase present, use the total height as the surfactant layer height,  $H_s = H_a$ .

#### Yield Stress and Zero Shear Viscosity Method:

The Yield Stress and Zero Shear Viscosity of a composition contained within a zone, can be measured either prior to combining the phases in a composition, or after combining the phases in a composition by separating the phases by suitable physical separation means, such as centrifugation, pipetting, cutting away mechanically, rinsing, filtering, or other separation means. In the case of testing from a product package, two zones can be selected from the package that contains at least two compositions that contain separate hydrophobic benefit material concentrations. In order to separate the zones, the product can be frozen at a temperature of at least  $-20^\circ\text{C}$  for a period of at least 24 hours. The zones are then cut using a cutting implement such as a bandsaw. The cut portions are collected separately and allowed equilibrate to ambient conditions.

A controlled stress rheometer, such as a TA Instruments AR2000 Rheometer, is used to determine the Yield Stress and Zero Shear Viscosity. The determination is performed at  $25^\circ\text{C}$  with the 4 cm diameter parallel plate measuring system and a 1 mm gap. The geometry has a shear stress factor of  $79580 \text{ m}^{-3}$  to convert torque obtained to stress. Serrated plates can be used to obtain consistent results when slip occurs.

First a sample of the composition is obtained and placed in position on the rheometer base plate, the measurement geometry (upper plate) moving into position 1 mm above the base plate. Excess phase at the geometry edge is removed by scraping after locking the geometry. If the phase comprises particles discernible to the eye or by feel (beads, e.g.) which are larger than about 150 microns in number average diameter, the gap setting between the base plate and upper plate is increased to the smaller of 4 mm or 8-fold the diameter of the 95<sup>th</sup> volume percentile particle diameter. If a phase has any particle larger than 5 mm in any dimension, the particles are removed prior to the measurement.

The determination is performed via the programmed application of a continuous shear stress ramp from 0.1 Pa to 1,000 Pa over a time interval of 4 minutes using a logarithmic progression, i.e., measurement points evenly spaced on a logarithmic scale. Thirty (30) measurement points per decade of stress increase are obtained. Stress, strain and viscosity are recorded. If the measurement result is incomplete, for example if material flows from the gap, results obtained are evaluated and incomplete data points excluded. The Yield Stress is determined as follows. Stress (Pa) and strain (unitless) data are transformed by taking their logarithms (base 10). Log(stress) is graphed vs. log(strain) for only the data obtained between a stress of 0.2 Pa and 2.0 Pa, about 30 points. If the viscosity at a stress of 1 Pa is less than 500 Pa-sec but greater than 75 Pa-sec, then log(stress) is graphed vs. log(strain) for only the data between 0.2 Pa and 1.0 Pa, and the following mathematical procedure is followed. If the viscosity at a stress of 1 Pa is less than 75 Pa-sec, the zero shear viscosity is the median of the 4 highest viscosity values (i.e., individual points) obtained in the test, the yield stress is zero, and the following mathematical procedure is not used. The mathematical procedure is as follows. A straight line least squares regression is performed on the results using the logarithmically transformed data in the indicated stress region, an equation being obtained of the form:

$$(1) \text{ Log(strain)} = m * \text{ Log(stress)} + b$$

Using the regression obtained, for each stress value (i.e., individual point) in the determination between 0.1 and 1,000 Pa, a predicted value of log(strain) is obtained using the coefficients m and b obtained, and the actual stress, using Equation (1). From the predicted log(strain), a predicted strain at each stress is obtained by taking the antilog (i.e.,  $10^x$  for each x). The predicted strain is compared to the actual strain at each measurement point to obtain a %variation at each point, using Equation (2).

$$(2) \% \text{variation} = 100 * (\text{measured strain} - \text{predicted strain}) / \text{measured strain}$$

The Yield Stress is the first stress (Pa) at which %variation exceeds 10% and subsequent (higher) stresses result in even greater variation than 10% due to the onset of flow or deformation of the structure. The Zero Shear Viscosity is obtained by taking a first median value of viscosity in Pascal-seconds (Pa-sec) for viscosity data obtained between and including 0.1 Pa and the Yield Stress. After taking the first median viscosity, all viscosity values greater than 5-fold the first median value and less than 0.2x the median value are excluded, and a second median viscosity value is obtained of the same viscosity data,

excluding the indicated data points. The second median viscosity so obtained is the Zero Shear Viscosity.

## VI. Method Of Manufacture

In one embodiment, the personal care articles as disclosed herein are manufactured by a dual phase filler. The dual phase filler is associated with storage vessels, a combiner, a blender and nozzle for filling multiple personal care compositions. An example of a dual phase filler and associated software is manufactured by Antonio Mengibar Packaging Machinery of Barcelona, Spain. The surfactant phase and benefit phase of the personal care compositions are stored in separate storage vessel; each vessel equipped with a pump and a hose assembly. A programmed filler profile of the dual-phase filler controls the pumping of specific ratios of the two phases of the personal care compositions which result in the zones within a package. The two phases of the personal care compositions are pumped from the storage tanks into a combiner where the two phases are combined. After the phases are combined; they are mixed in a blender. From the blender, the resultant product is pumped via a hose into a single nozzle. The nozzle is placed into a container and fills a product package with a single resulting product. In some embodiments, the resultant product exhibits a distinct pattern of the phases which are visually distinct. In other embodiments, the resultant product exhibits a uniform appearance without a pattern. If a pattern is present, the pattern is selected from the group consisting of striped, marbled, geometric, and combinations thereof.

In other embodiments, the personal care compositions used in accordance with the present disclosure are manufactured according to the method disclosed in U.S. Patent Application No. 10/837,214 Publication No. 2004/0219119 A1 entitled "Visually distinctive multiple liquid phase compositions" filed by Wei et al. on April 30, 2004, published on November 18, 2004. Alternatively, it may be effective to combine toothpaste-tube filling technology with a spinning stage design. In still other embodiments, the personal care compositions are prepared by the method and apparatus as disclosed in U.S. Patent No. 6,213,166 issued to Thibiant et al. on April 10, 2001. The method and apparatus allow two or more compositions to be filled with a spiral configuration into a single product package. The method requires that at least two nozzles be employed to fill the compositions into a package. The package is placed on a moving stage and spun as the composition is introduced into the package.

Non-limiting examples of the personal care compositions, ratios of phases and filler profiles are disclosed in the examples below.

## VII. Composition and Articles EXAMPLES

### EXAMPLE 1. Exemplary Personal Care Articles

Table 5 shows non-limiting examples of the personal care articles as disclosed herein and a comparative example. These personal care articles are made and filled in a single chamber package. The personal care compositions used in accordance with the present disclosure comprise various concentrations of hydrophobic benefit material through out the package. These personal care compositions used in accordance with the present disclosure are filled in a package within multiples zones. The comparative example comprises uniform concentration of hydrophobic benefit material through out the package.

	Inventive Example A	Inventive Example B	Comparative Example C
<b>Surfactant Phase Composition</b>			
Sodium Lauroamphoacetate <sup>1.</sup>	4.9	4.9	4.9
Sodium Trideceth Sulfate <sup>2.</sup>	8.4	8.4	8.4
Sodium Lauryl Sulfate	8.4	8.4	8.4
Trideceth-3 <sup>3.</sup>	2.0	2.0	2.0
Sodium Chloride	4.75	4.75	4.75
Guar hydroxypropyltrimonium chloride <sup>4.</sup>	0.6	0.6	0.6
Polyethyleneoxide <sup>5.</sup>	0.15	0.15	0.15
Xanthan gum <sup>6.</sup>	0.2	0.2	0.2
Hollow microspheres <sup>7.</sup>	0.36	0.3	0.3
Methyl chloro isothiazolinone and methyl isothiazolinone <sup>8.</sup>	0.0005	0.0005	0.0005
EDTA <sup>9.</sup>	0.15	0.15	0.15
Sodium Benzoate	0.2	0.2	0.2
Citric Acid, titrate	pH=5.7 ± 0.2	pH = 5.7 ± 0.2	pH = 5.7 ± 0.2
Perfume	1.3	1.3	1.3
Water	Q.S.	Q.S.	Q.S.
<b>Benefit Phase Composition</b>			
Petrolatum <sup>10.</sup>	70	70	70
Mineral Oil <sup>11.</sup>	30	30	30
Filler Profile	Inventive Profile A	Inventive Profile B	Comparative Profile C

<sup>1.</sup> available from Cognis Chemical Corp. <sup>2.</sup> sulfanated to >95% sulfate from ICONOL® TDA-3 available from BASF Corp., <sup>3.</sup> ICONOL® TDA-3 available from BASF Corp., <sup>4.</sup> N-HANCE® 3196 Polymer from Aqualon of Wilmington, DE, <sup>5.</sup> POLYOX™ WSR-301

available from DOW® Chemical Corp., <sup>6</sup>KELTRO™ 1000 available from CP Kelco, <sup>7</sup>EXPANCEL® microspheres available from 091 WE40 d24, Akzo Nobel, <sup>8</sup>KATHON® CG available for Rohm & Haas, <sup>9</sup>DISSOLVINE® NA 2x available from Akzo Nobel, <sup>10</sup>G2218 petrolatum from Sonneborn, <sup>11</sup>HYDROBRITE® 1000 White Mineral Oil available from Sonneborn.

The compositions described above can be prepared by conventional formulation and mixing techniques. The surfactant phase composition is made by first preparing a citric acid premix and then a polymer pre-mix. The citric acid premix is prepared by adding citric acid into water at a ratio of 1:3. The polymer premix is prepared by adding polyethyleneoxide and xanthan gum into trideceth-3. The following ingredients are then added into the main mixing vessel in the following sequence with agitation: water, guar hydroxypropyltrimonium chloride, hollow microspheres, sodium lauroamphoacetate, sodium trideceth sulfate, sodium lauryl sulfate, sodium chloride, sodium benzoate, and disodium EDTA. The citric acid premix is added into the main mixing vessel and the pH of the composition is adjusted to  $5.7 \pm 0.2$ . The polymer premix is next added into the main mixing vessel with continuous agitation. Perfume and methyl chloro isothiazolinone and methyl isothiazolinone are added while continuing the agitation until the composition is homogeneous. The resultant surfactant phase composition is fed into the dual-phase filler through a hose-assembly.

The benefit phase composition is prepared by first adding petrolatum into a mixing vessel. The mixing vessel has been heated to 82.2°C. Mineral oil is added into the mixing vessel with agitation. The benefit phase composition is cooled to 44°C through a scraped-wall heat-exchanger, such as that manufactured by Waukesha Cherry-Burrell, Delavan, WI. After cooling, the resultant benefit phase composition is fed into the dual-phase filler through a second hose-assembly.

The filler profiles A, B and C are examples of filling programs that specify the ratios of the surfactant and benefit phases within packages filled by a dual phase filler. Filler profiles A and B specify variable hydrophobic benefit material concentrations throughout the zones of the personal care articles as disclosed herein. Whereas filler profile C specifies uniform hydrophobic benefit material concentrations in the resultant personal care article within the package.

Table 6: Dual Phase Filler Profiles for Example A and B	
Filler Profile A	Filler Profile B

Step	Dose (mL)	Benefit Material %	Surfactant %	Step	Dose (mL)	Benefit Material %	Surfactant %
1	33.6	24	76	1	33.2	30	70
2	61.4	42	58	2	61.7	50	50
3	70.6	52	48	3	71.2	60	40
4	104.2	63	37	4	104.4	70	30
5	133.2	63	37	5	132.9	60	40
6	155.2	52	48	6	154.7	50	50
7	174.9	42	58	7	194.6	40	60
8	194.5	32	68	8	223.1	20	80
9	223.5	15	85	9	248.7	10	90
10	249.0	7	93	10	280.0	20	80
11	280.2	15	85	11	289.5	30	70
12	289.5	27	73	---	---	---	---

Table 7: Dual Phase Filler Profiles for Example C

Filler Profile C			
Step	Dose (mL)	Benefit Material %	Surfactant %
1	11	45	55
2	20	45	55
3	35	45	55
4	52	45	55
5	75	45	55
6	108	45	55
7	148	45	55
8	188	45	55
9	229	45	55
10	265	45	55
11	280	45	55

FIG. 20 depicts MRI images that illustrate the surfactant and hydrophobic benefit material distribution in a package of examples A, B and C. These images were taken by the MRI Method, described in detail in the Test Methods above. As shown in FIG. 20, the comparative example C shows a uniform hydrophobic benefit material distribution throughout the package. Inventive examples A and B, in FIG. 20 show a variable hydrophobic benefit material distribution profile with higher benefit zones are highlighted with arrows.

FIG. 21 is a chart of the hydrophobic benefit material distribution in examples A and B as disclosed herein. The Micro centrifugation Method, described in detail in the Test Methods above, was used to quantify the hydrophobic benefit material distribution in the



inventive examples A and B. Profile A and profile B, shown in FIG. 21 clearly show a variable benefit distribution from the beginning, middle, and end of the dispensing.

Referring to FIG. 22, a package 10 suitable for receiving a personal care composition is shown. The package 10 comprises a plurality of sections 12, 14, 16, and 18 that are separable from each other. As described further hereafter, the package 10 can be used in a quality assurance method to assess the profiles of the hydrophobic benefit material and/or a surfactant benefit material (or other materials) after a filling operation. In one embodiment the package 10 is part of a quality assurance check in a high speed manufacturing line, wherein after a filling operation the sections 12, 14, 16, and 18 of package 10 are separated and the personal care composition in each section is separately analyzed to determine the amount/volume of hydrophobic benefit material and/or surfactant material by weight of the personal care composition in the separated section. The analysis of the benefit materials can be performed using any of the methods (or others) described herein. The centrifuge and/or MRI methods described herein may be used in one embodiment. These material profiles can be combined to yield an overall material profile curve for the package 10, similar to that shown in FIG. 21, of the hydrophobic benefit material and/or surfactant benefit material which can be compared to a manufacturing specification for the product.

The sections 12, 14, 16, and 18 can be held together by one or more fasteners (not shown), such as a screw or bolt, as known in the art. In one embodiment, two screws extend from section 12 through to section 18 thereby interconnecting each of sections 12, 14, 16, and 18. When the two screws are removed, each of the section 12, 14, 16, and 18 can be fully separated from each other as shown in FIG. 23. Alternatively, a separate fastener could be employed between each section, although this would necessitate removal of more than 2 fasteners to separate all of the sections 12, 14, 16, and 18. While four sections 12, 14, 16, and 18 are shown, it will be appreciated that more (or fewer) sections can be provided depending upon the desired resolution of the overall material profile curve for the package 10. For example, increasing the number of separable sections should provide a higher resolution because more data points are generated for the profile curve of the package. In one embodiment, the package 10 comprises between 2 and 8 sections and in other embodiments the package 10 comprises between 4 and 6 sections.

Referring to FIG. 24, a high speed manufacturing line 20 is shown schematically. The manufacturing line 20 comprises a filling station 22 that simultaneously receives a plurality of

containers 24 comprising a plurality of consumer packages 26 and one or more packages 10. The consumer packages 26 are non-separable and intended for eventual distribution to an end user or consumer after filling with a personal care composition, such as a rinse-off body wash. As shown in FIG. 24, the package 10 can be provided to the filling station 22 intermittently with the plurality of containers 24.

In one embodiment, the filling station 22 comprises two tanks 28 and 30. Tank 28 contains a first composition comprising the hydrophobic benefit material, and tank 30 contains a second composition comprising one or more surfactants. The first and second compositions can be mixed as discussed previously. While two tanks are shown, it will be appreciated that more tanks and compositions can be provided as desired. The tanks 28 and 30 are connected by hose assemblies to a filler 34 comprising a plurality of nozzles 32. The first and second compositions are pumped from the tanks 28 and 30 to the filler 34. There is a nozzle for filling each of the plurality of containers 24. Each nozzle is configured so that the first and second compositions are dispensed simultaneously into each container according to a predetermined ratio that can vary along the length of the container, an exemplary predetermined ratio being described in Table 3. The first and second compositions thereby form the personal care composition that is dispensed from the container during use. The filling station 22 can be configured so that the filler 34, along with the plurality of nozzles 32, can be displaced vertically toward and away from the plurality of containers 24 during a filling operation so an appropriate profile of the first and second compositions can be achieved along the length of a container.

After a filling operation is complete, the plurality of filled containers 24 are moved away from the filling station 22 by a conveyor 34, and a new set of unfilled containers are moved into position within the filling station 24. As shown in FIG. 24, the new plurality of containers 24 may omit the separable package 10. The package 10 is removed from the manufacturing line 20 after filling.

After removal of the package 10 from the manufacturing line 20, the sections 12, 14, 16, and 18 are separated from each other along with the dosage of the personal care composition disposed within each section. In the context of a personal care compositions that is a rinse-off type body wash, the viscosity is typically such that the dosages of the personal care composition disposed within each section of the package 10 tends to stay within its section after separation of the sections from each other. The personal care composition within each

section of package 10 can then be removed from its section of package 10 and individually analyzed to determine the amount of hydrophobic benefit material that section of the package 10. The Micro-Centrifugation Method described previously may be used to determine the amount of hydrophobic material present in the one or more sections of the package 10, although other methods may also be employed in combination with or as substitute for the Micro-Centrifugation Method. For example, the MRI Method might be used in combination with the Micro-Centrifugation method, wherein the package 10 is imaged by an MRI machine before separating the sections of the package to obtain the dosages of the personal care composition for micro-centrifuge testing.

Once the dosage of the personal care composition has been separated/dispensed from its section and analyzed, a curve can be plotted that represents the variation of the concentration of the hydrophobic material (or some other material) along the length of the package 10 by weight of either the dosage of the personal care composition within a section of the package 10 or by overall weight of the personal care composition within the entire package 10. This curve can be compared to a known calibration curve to determine whether the manufacturing process is within limits or if corrective action is necessary in order to assure that the containers are filled according to the desired profile.

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."

All documents cited in the Detailed Description are, in relevant part, incorporated herein by reference; the citation of any document is not to be construed as an admission that it is prior art with respect to the present disclosure. 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 incorporated by reference, the meaning or definition assigned to that term in this document shall govern.

While particular embodiments as disclosed herein have been illustrated and described, it would be obvious to those skilled in the art that various other changes and modifications can be made without departing from the spirit and scope of the disclosure. It is therefore

intended to cover in the appended claims all such changes and modifications that are within the scope of this disclosure.

We claim:

1. A method for providing a personal skin care article with an optimized user experience profile, the method comprising:

identifying a target population,

developing a population profile with respect to a rinse-off personal care composition used for cleansing and moisturizing comprising the steps of

determining the population preferences for maximum amount of hydrophobic benefit agent, and

determining the population preferences for lather volume, lather texture, and lathering speed, composition thickness, color, translucence, opalescence, and scent

formulating a personal care composition reflecting a population profile, wherein the composition comprises varying ratios of a lathering agent to a hydrophobic benefit agent,

configuring a delivery article adapted to dispense the composition in discrete aliquots and to contain the composition so as to dispense the composition in stages comprising at least:

a first stage comprising a first ratio of the varying ratios of lathering agent to hydrophobic benefit agent,

a second stage comprising a second ratio of the varying ratios of lathering agent to hydrophobic benefit agent that is different than the first ratio;

manufacturing the composition for the target population;

providing the composition in the delivery article.

2. The method according to claim 1, wherein the steps are repeated for a different target population.

3. The method according to claim 1, comprising a third stage comprising a third ratio of the varying ratios of lathering agent to hydrophobic benefit agent that is different than the second ratio;

wherein

(i) the ratio in the second stage is lower than the ratio in the first stage, and wherein the ratio in the third stage is the same as or lower than the ratio in the first stage; or

(ii) the ratios of lathering agent to hydrophobic benefit agent vary continuously from the start of the first stage through the end of the third stage.

4. The method according to any one of the preceding claims, wherein the ratios of lathering agent to hydrophobic benefit agent vary continuously through at least a portion of the stages.
5. The method according to claim 3, wherein the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 75:25 in the first stage, and the ratio of lathering agent to hydrophobic benefit agent is at a minimum of about 45:55 in the second stage, and the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 75:25 in the third stage.
6. The method according to claim 3, wherein the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 70:30 in the first stage, and the ratio of lathering agent to hydrophobic benefit agent is at a minimum of about 45:55 in the second stage, and the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 80:20 in the third stage.
7. The method according to claim 3, wherein the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 75:25 in the first stage, and the ratio of lathering agent to hydrophobic benefit agent is at a minimum of about 45:55 in the second stage, and the ratio of lathering agent to hydrophobic benefit agent is at a maximum of about 75:25 in the third stage.
8. The method according to claim 3, wherein the ratio of lathering agent to hydrophobic benefit agent is in the range from about 10:90 to 90:10 in the first stage, and the ratio of lathering agent to hydrophobic benefit agent is in the range from about 10:90 to 90:10 in the second stage, and the ratio of lathering agent to hydrophobic benefit agent is in the range from about 10:90 to 90:10 in the third stage.
9. The method according to any one of the preceding claims, wherein the lather volume is greater than 800ml to 1500ml by the cylinder lather method.
10. The method according to any one of the preceding claims, wherein the lather volume is greater than 800 ml.
11. The method according to any one of the preceding claims, wherein the lather volume is greater than 1000 ml.
12. The method according to any one of the preceding claims, wherein the lather volume is greater than 1500 ml.
13. The method according to any one of the preceding claims, wherein each aliquot dispensed by the article is of approximately equal volume.

14. The method according to claim 1, wherein the composition comprises a first composition comprising the lathering agent and a second composition comprising the hydrophobic benefit agent, and wherein the ratio of the first comp to the second comp varies through the delivery article.

15. The method according to claim 14, comprising identifying a second target population, developing a population profile for the second population, and formulating a personal care composition wherein the varying ratios in at least one of the first and second stages for the second target population are different as compared to the varying ratios in at least one of the first and second stages for the first population.

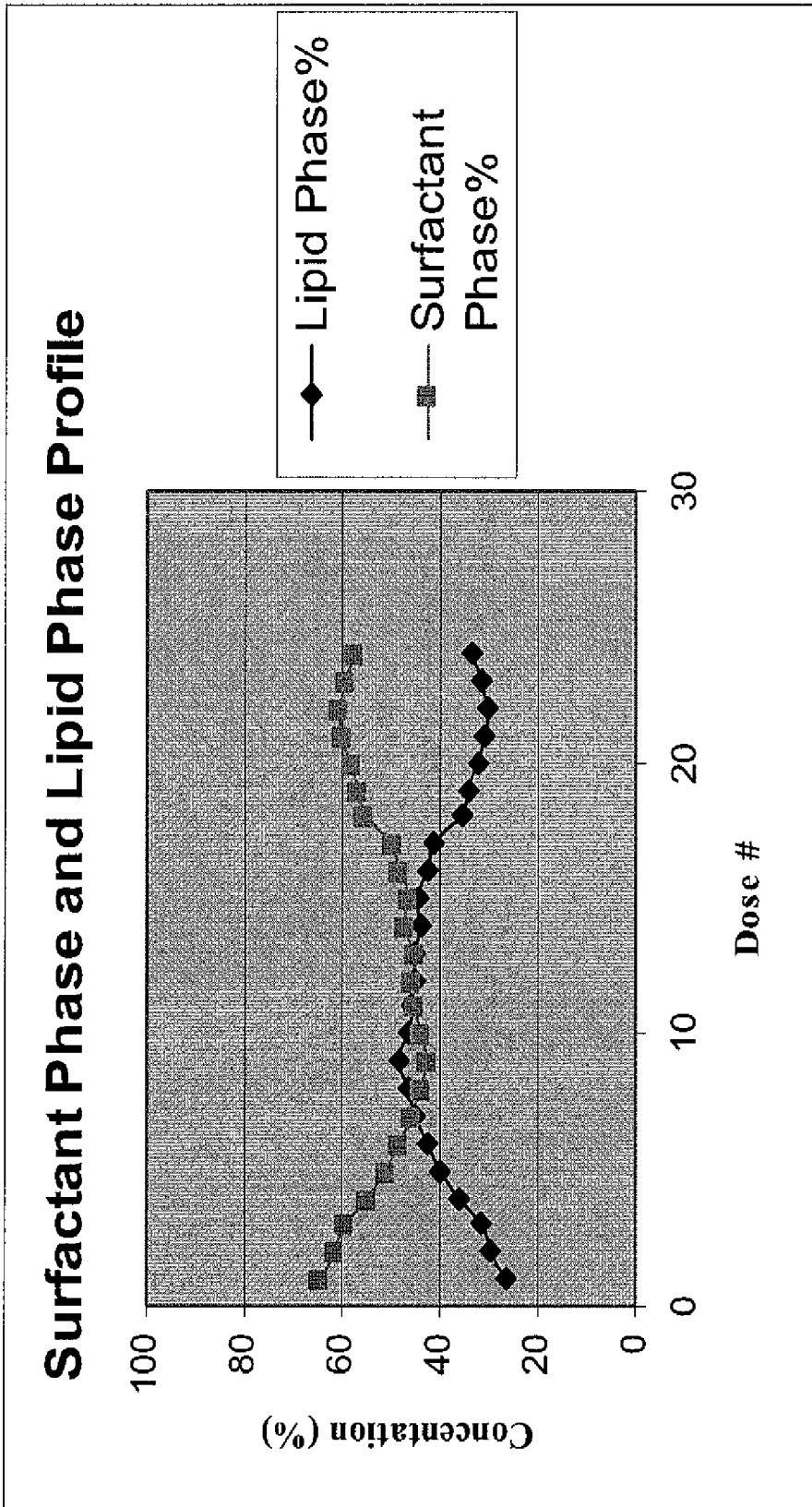


FIG. 1



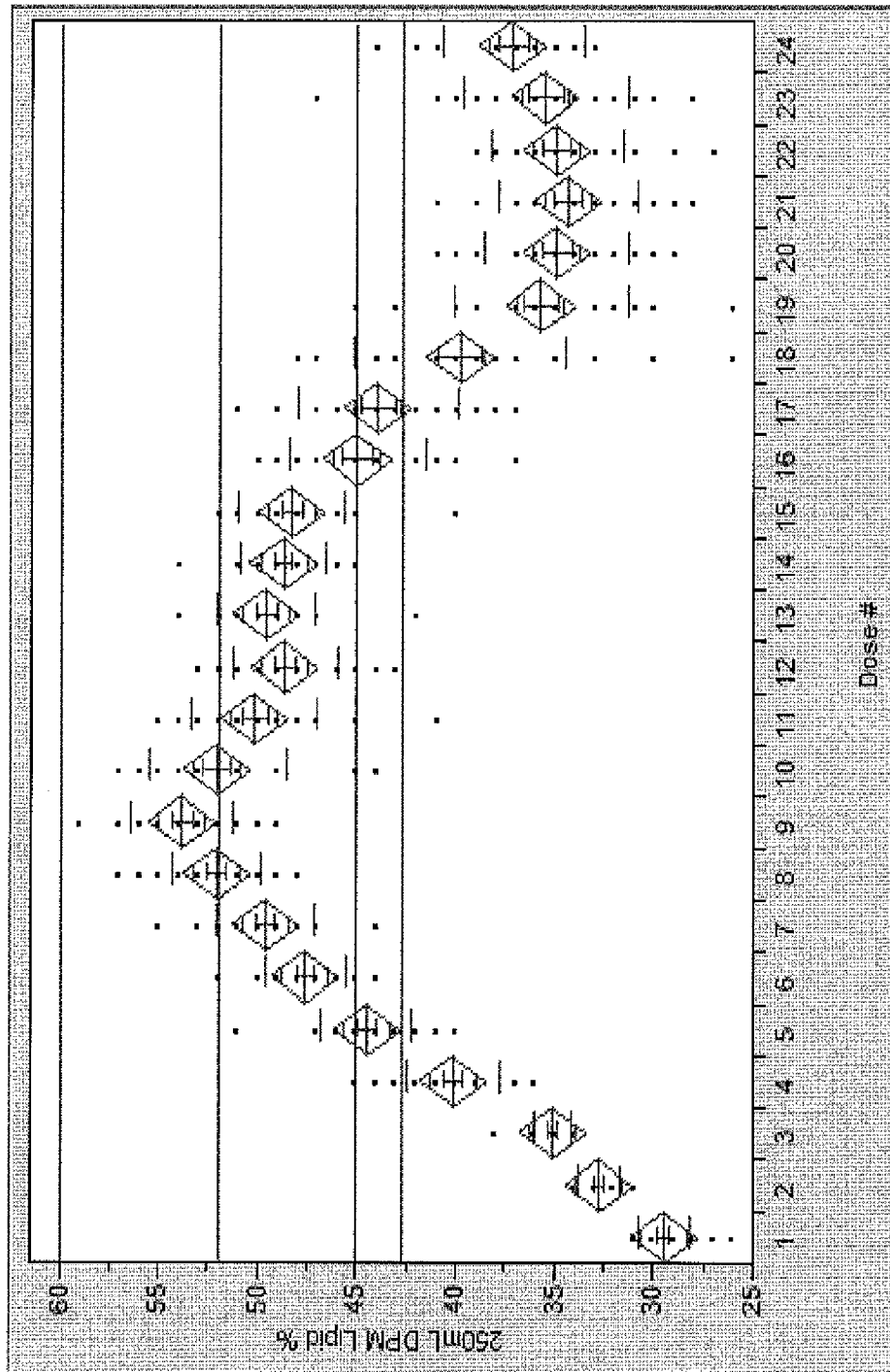


FIG. 2

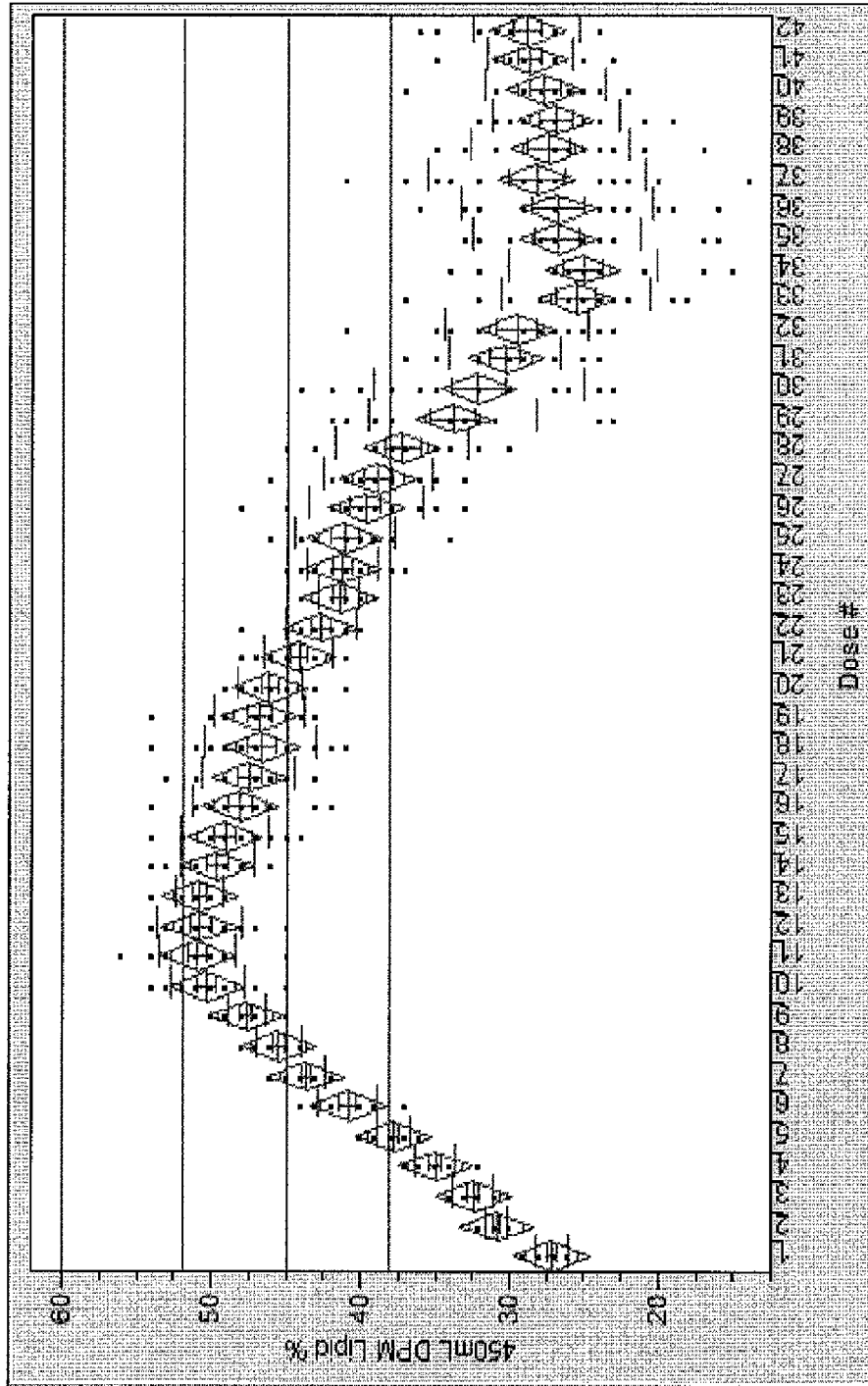
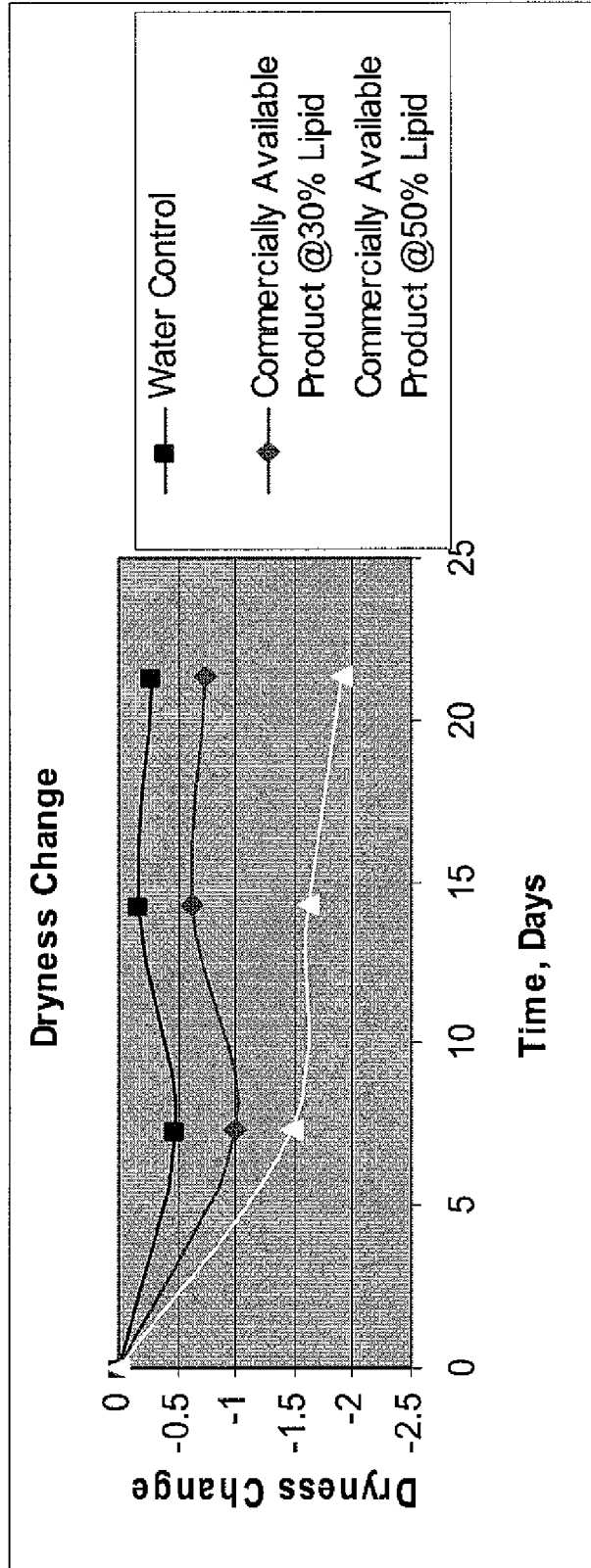


FIG. 3

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Visual Dryness Change:  
30% Lipid vs. 50% Lipid



\*Data plotted using 3 hours after specified visit.

FIG. 4

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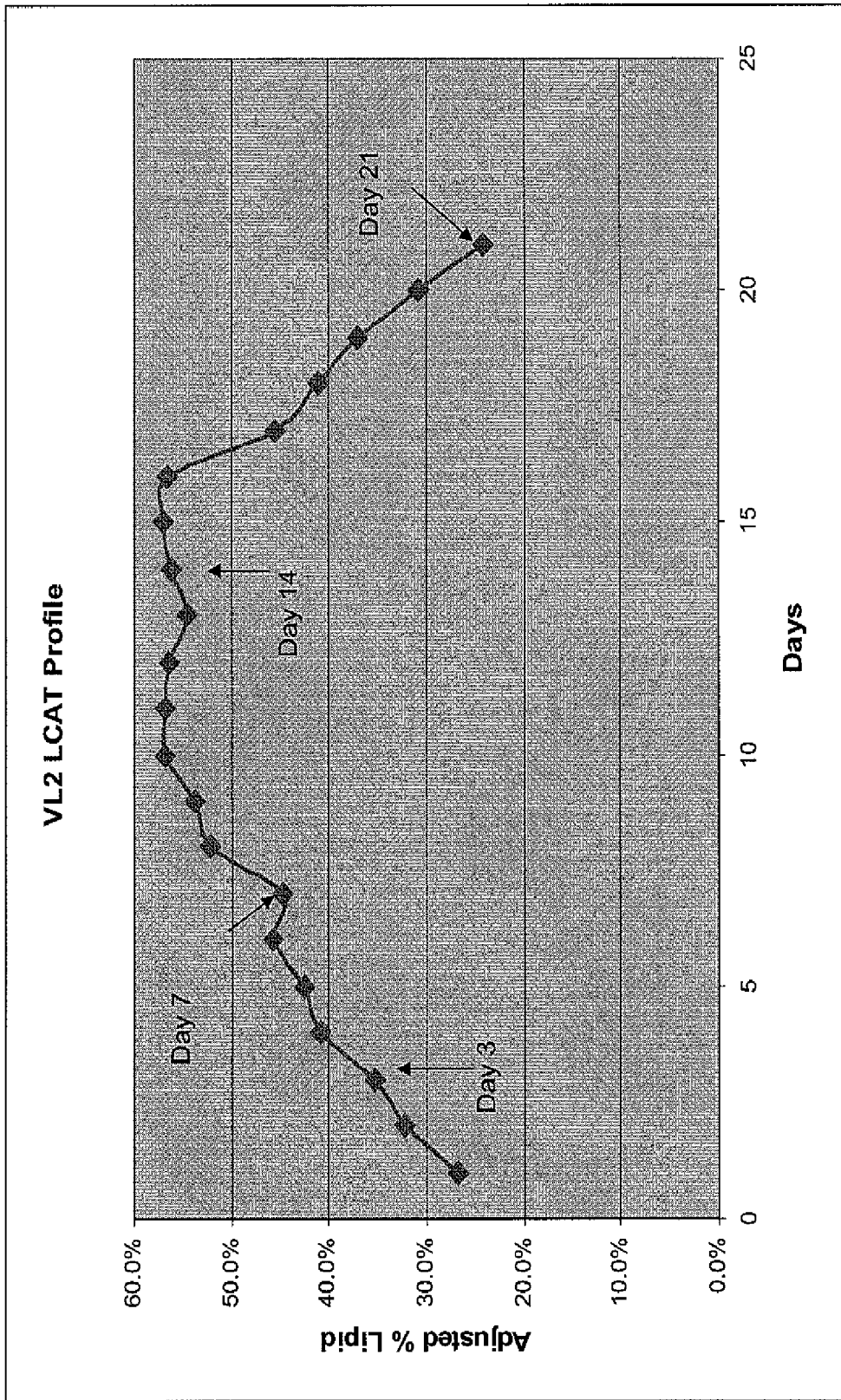
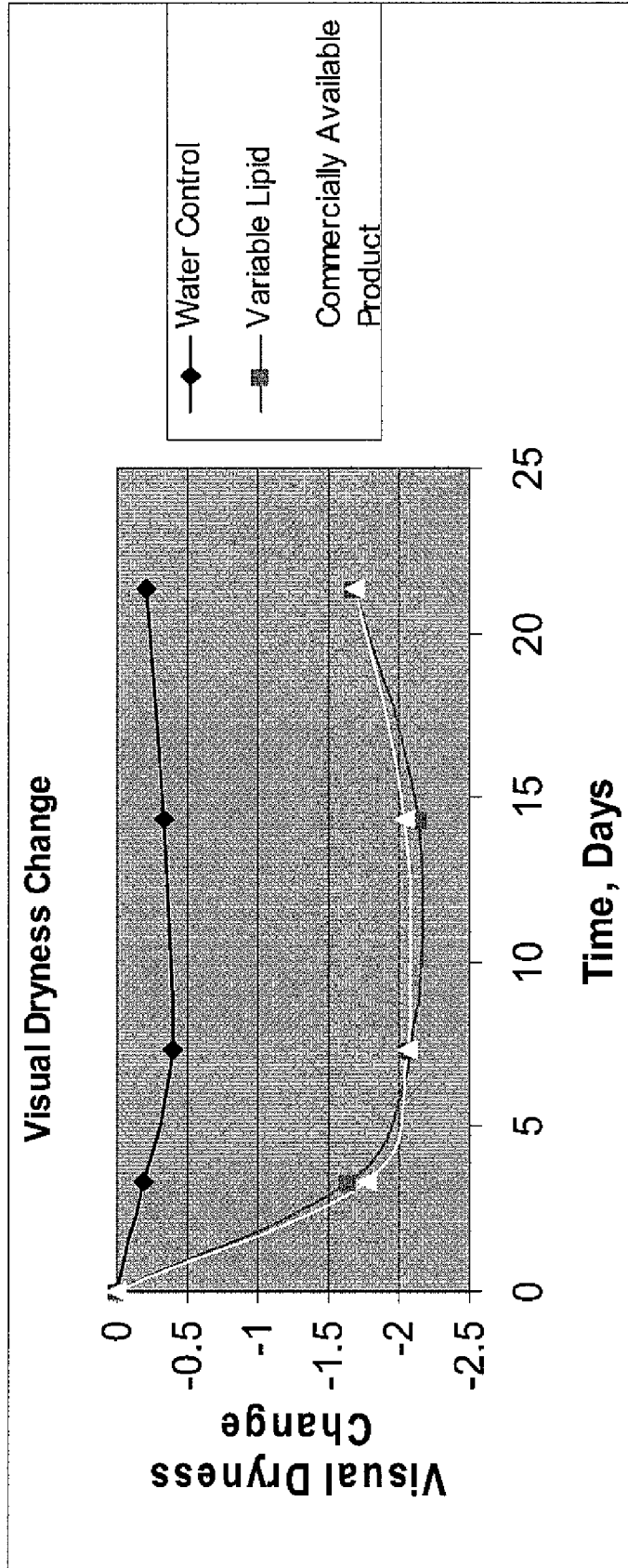


FIG. 5

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# Visual Dryness Change

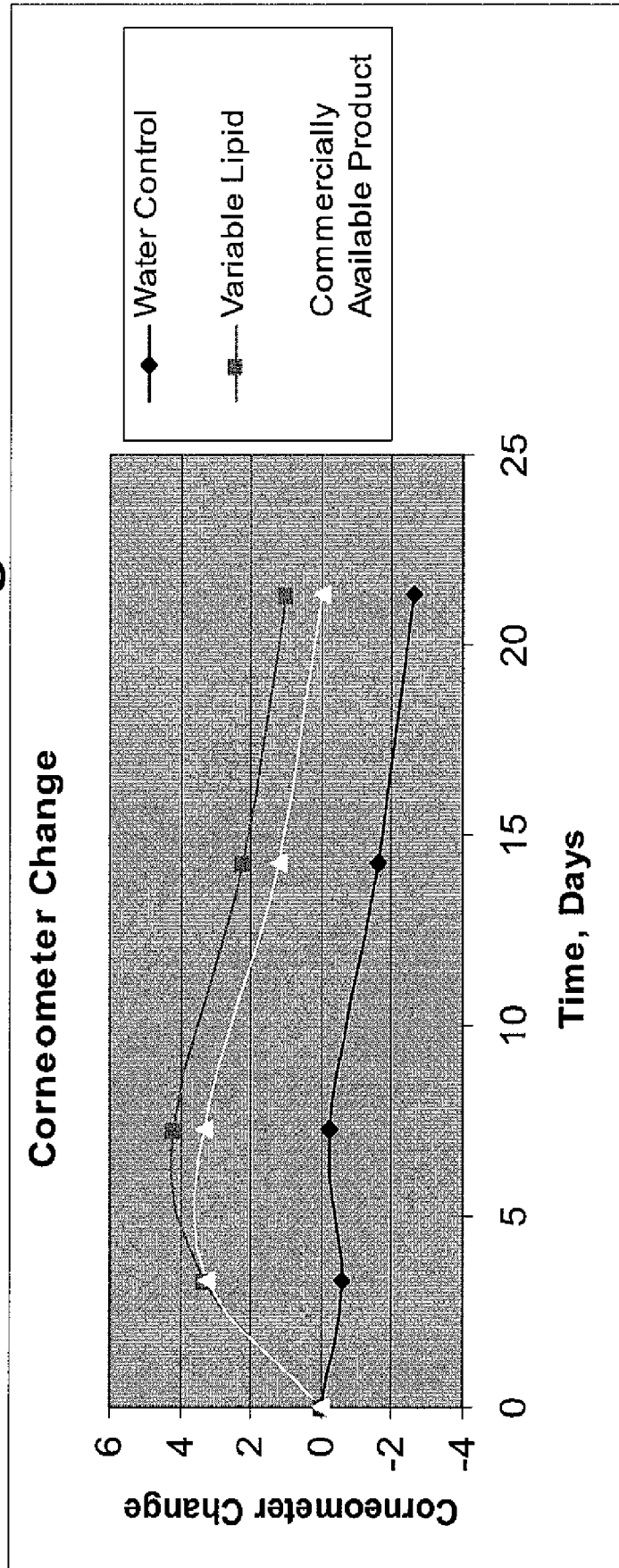


\*Data plotted using 3 hours after specified visit.

FIG. 6

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# Corneometer Change

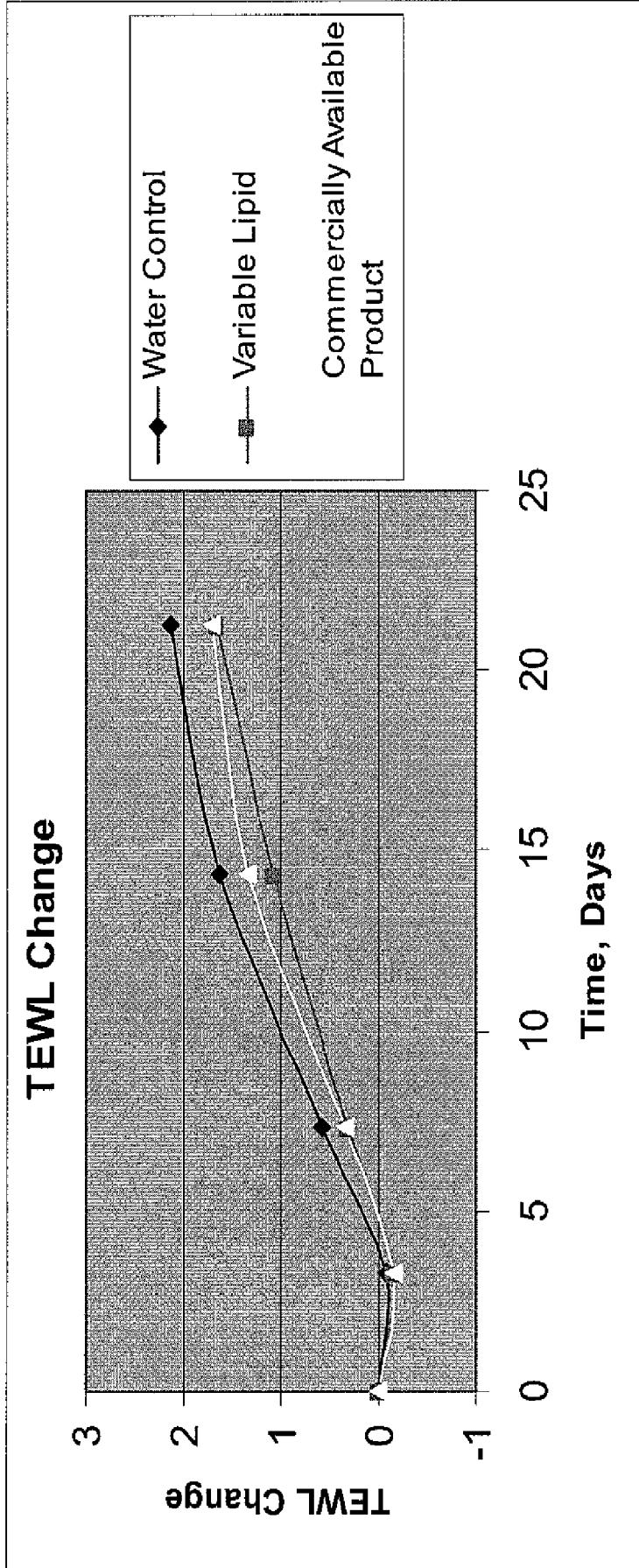


\*Data plotted using 3 hours after specified visit.

FIG. 7

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# TEWL Change



\*Data plotted using 3 hours after specified visit.

FIG. 8

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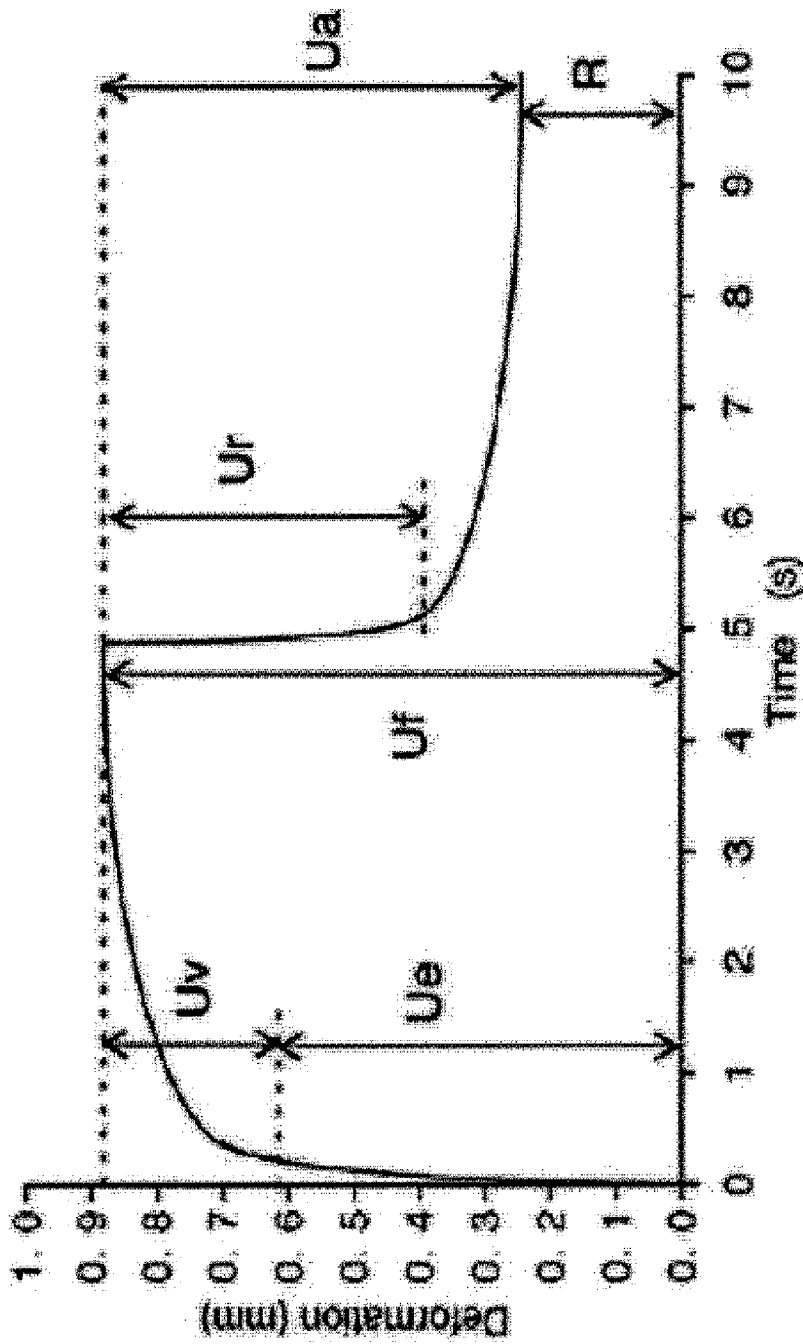
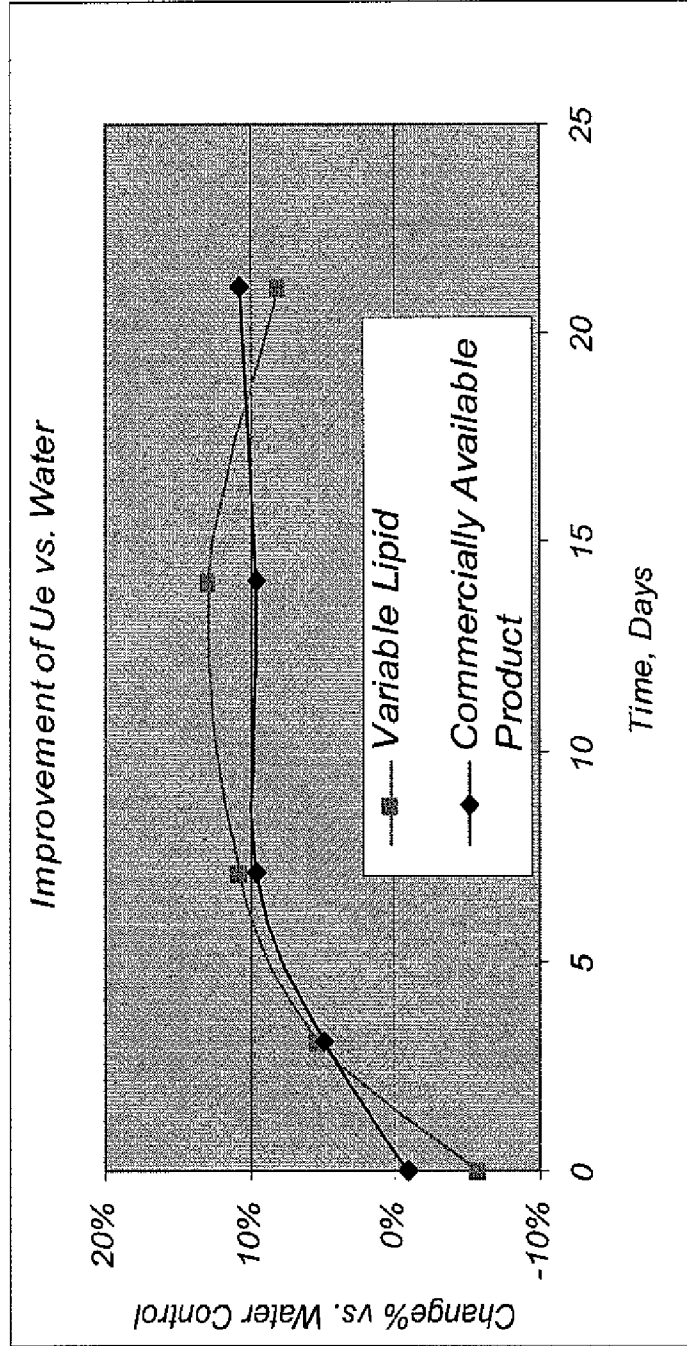


FIG. 9



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# Cutometer Measures: Change in Ue

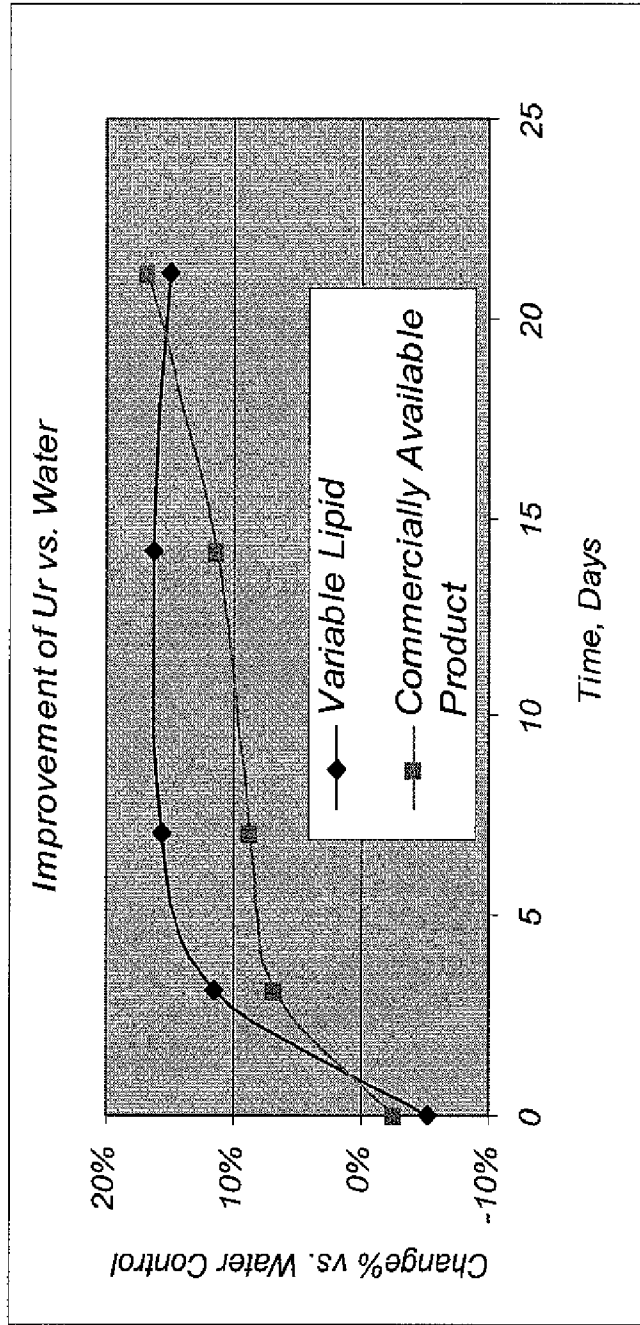


\*Cutometer data taken at 1 hour after specified visit.

**FIG. 10**

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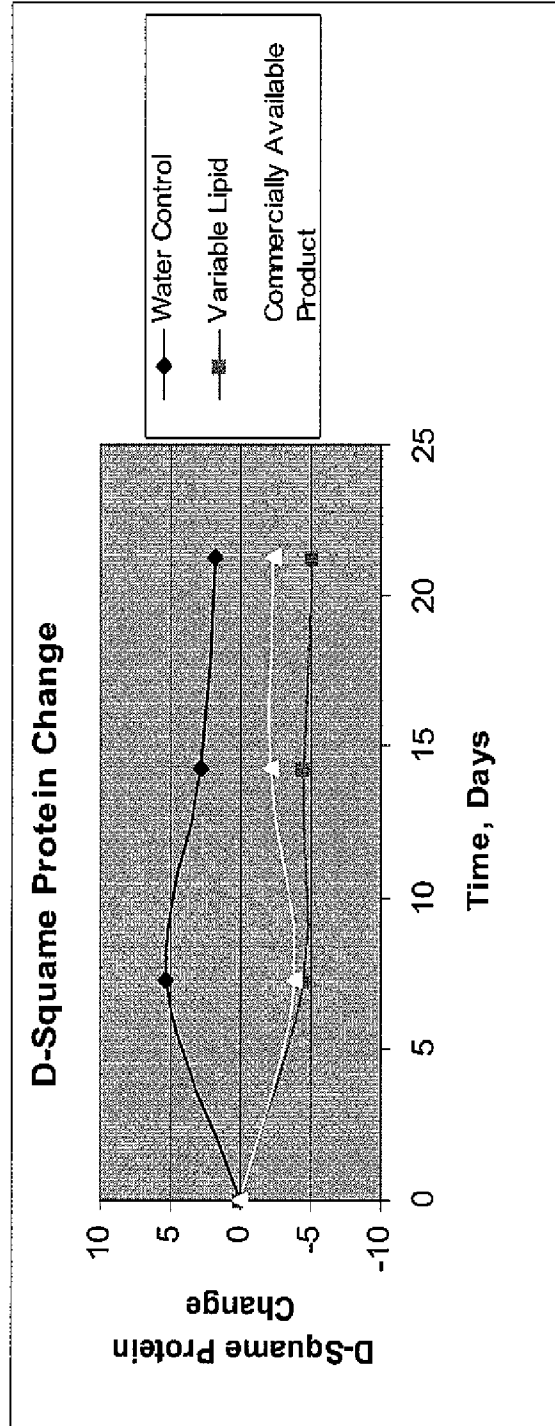
# Cutometer Measures: Change in Ur



\*Cutometer data taken at 1 hour after specified visit.

**FIG. 11**

# D-Squame Protein Change



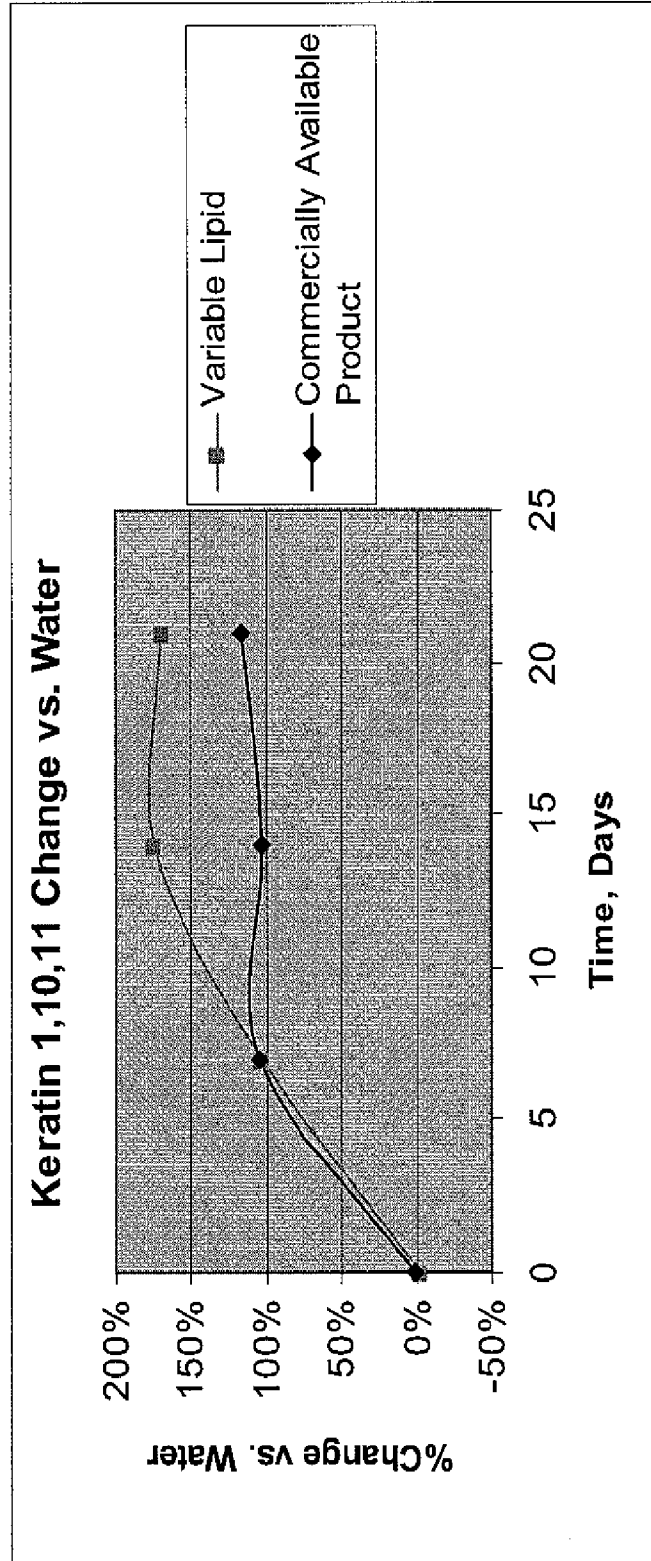
12/2

\*D-squame tape strip taken 24 hour after specified visit.

**FIG. 12**

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# Keratin 1,10,11 Normalized to Soluble Protein



\*D-squame tape strip taken 24 hour after specified visit.

**FIG. 13**

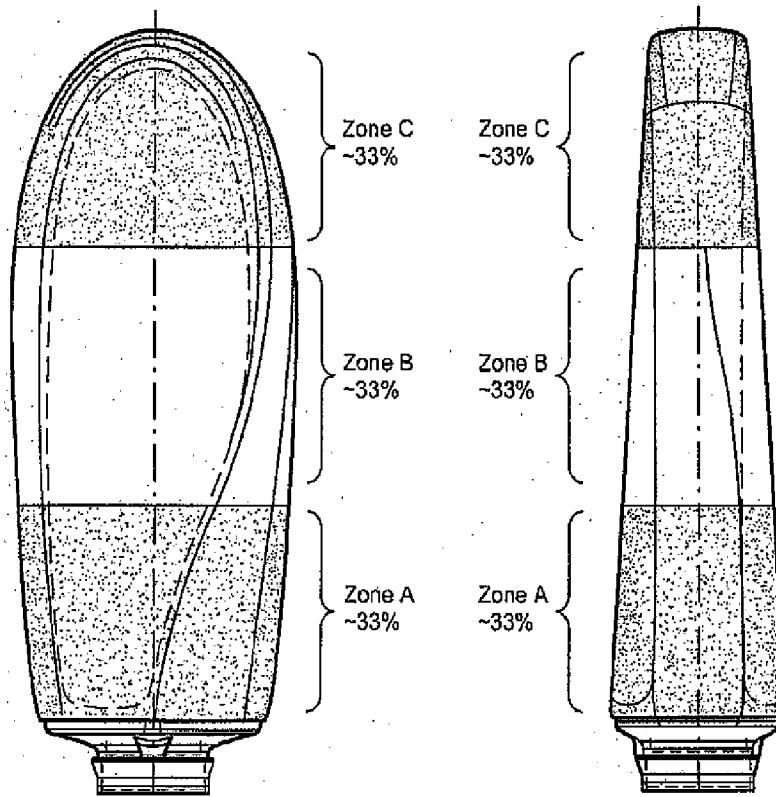


FIG. 14A

FIG. 14B

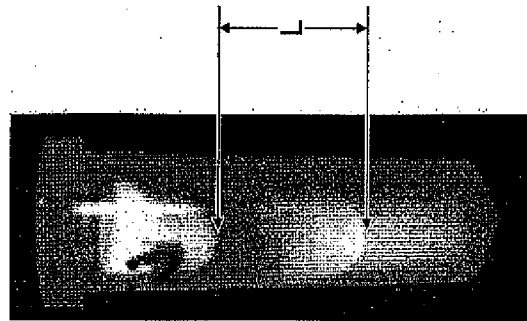


FIG. 15C

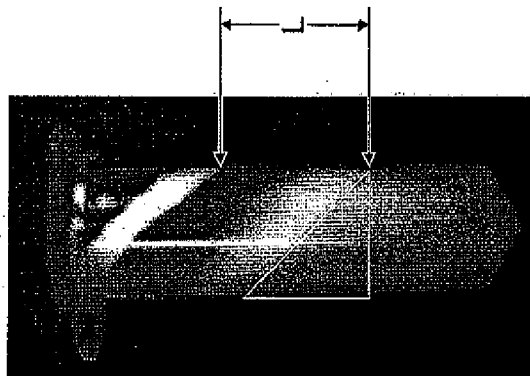


FIG. 15B

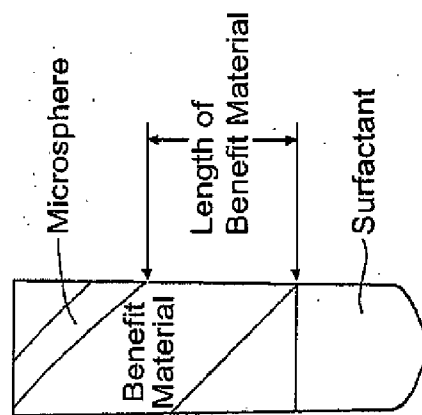


FIG. 15A

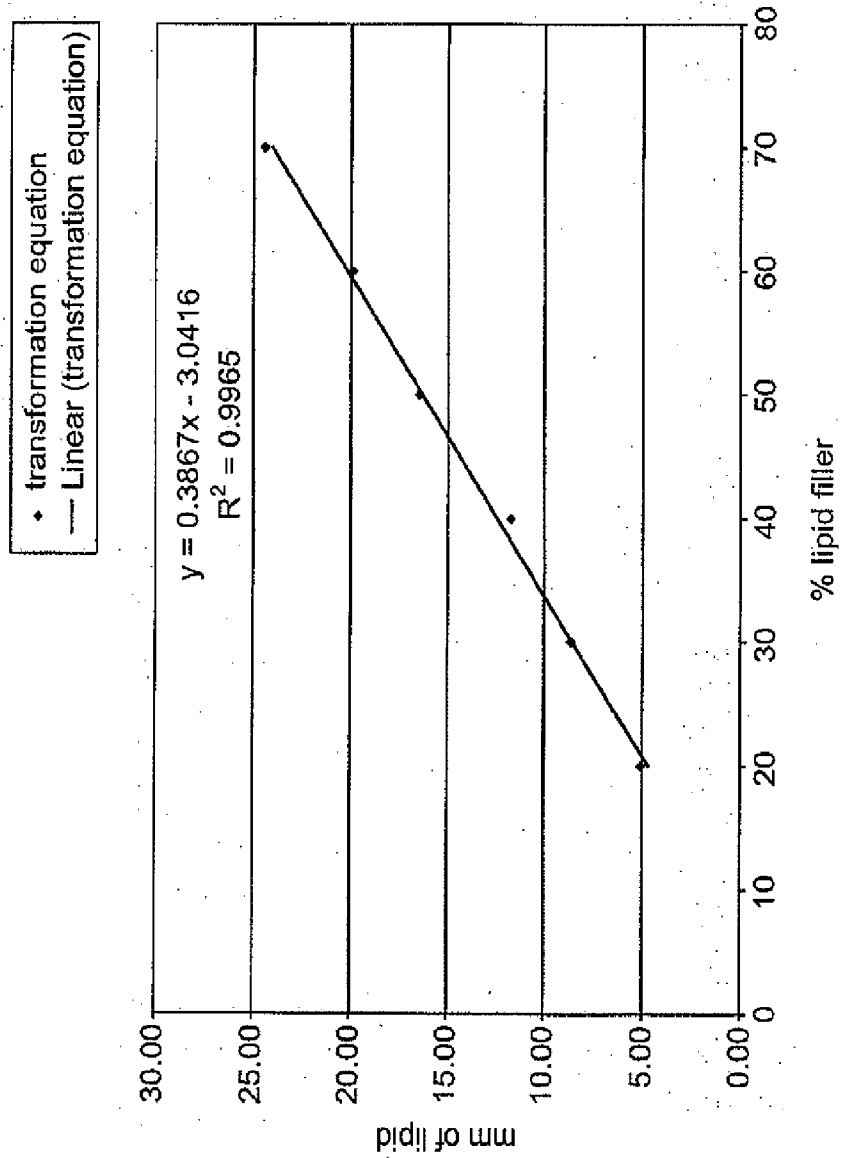


FIG. 16

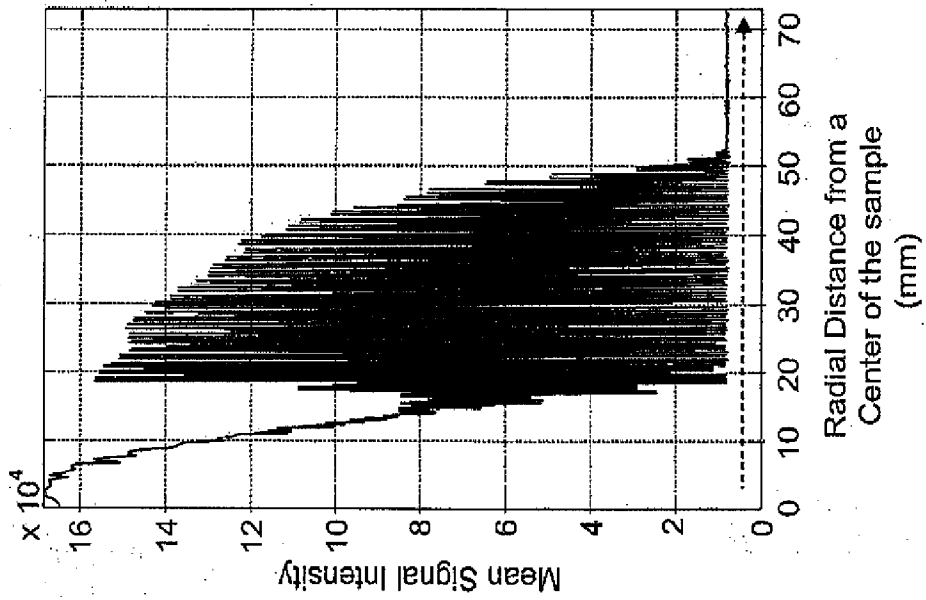


FIG. 17B

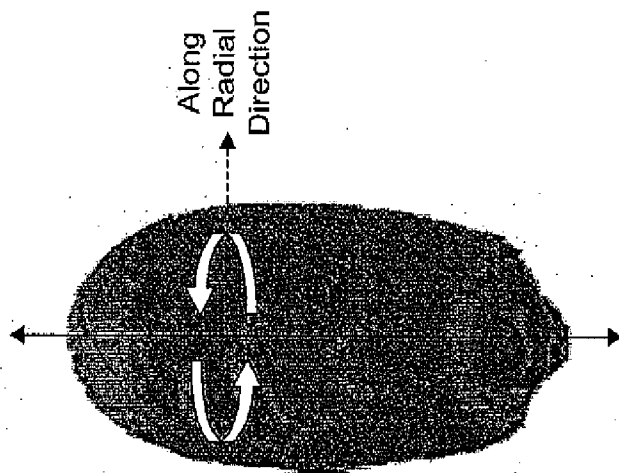


FIG. 17A



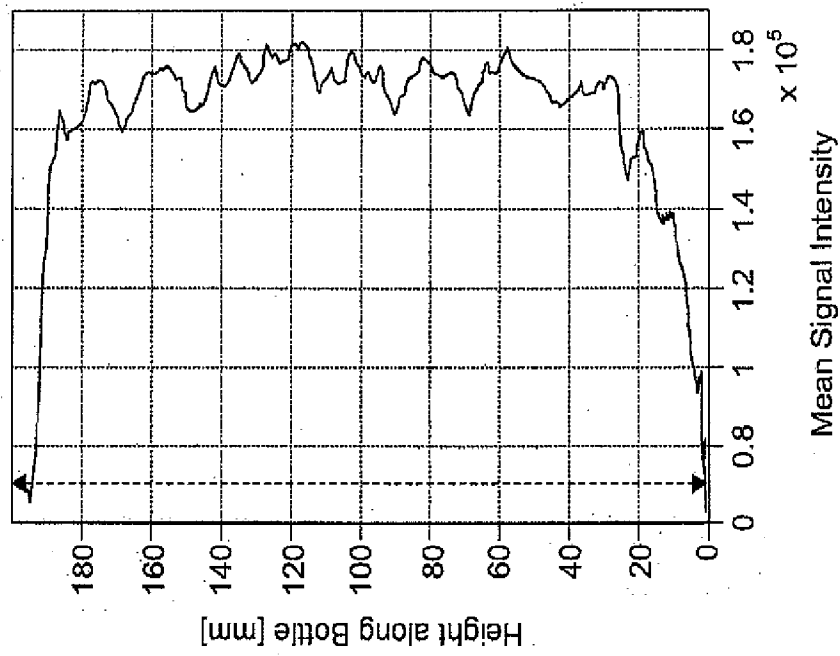


FIG. 18B

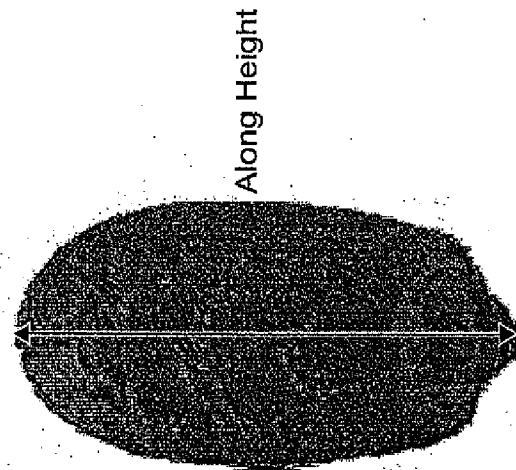
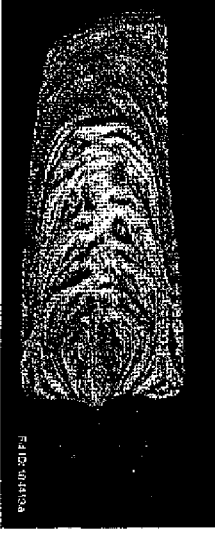

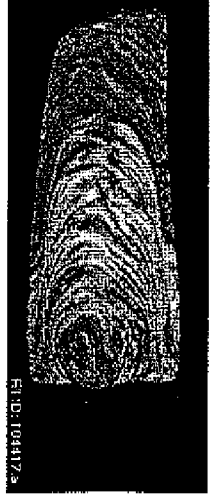

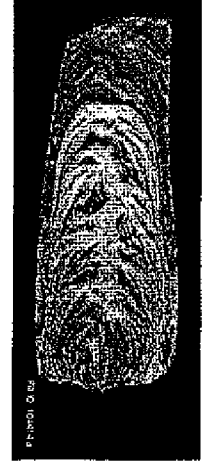
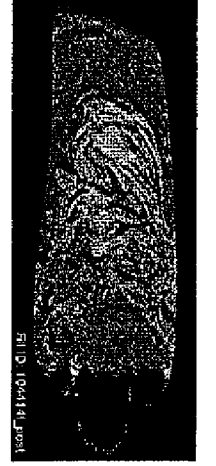


FIG. 18A

Head Space	Before Simulated Shipping Conditions	After Simulated Shipping Conditions	Results
<p>FIG. 19A</p> <p>16% Headspace</p>			<p>Failed Shipping Stability</p>
<p>FIG. 19B</p> <p>10% Headspace</p>			<p>Improved Shipping Stability</p>
<p>FIG. 19C</p> <p>3% Headspace</p>			<p>Passed Shipping Stability</p>

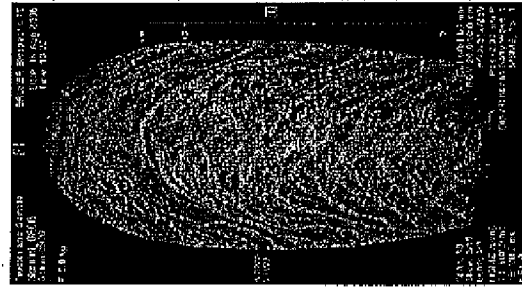


FIG. 20C

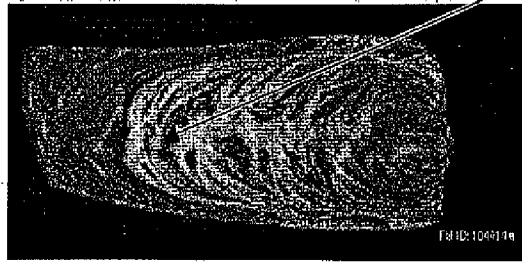


FIG. 20B



FIG. 20A

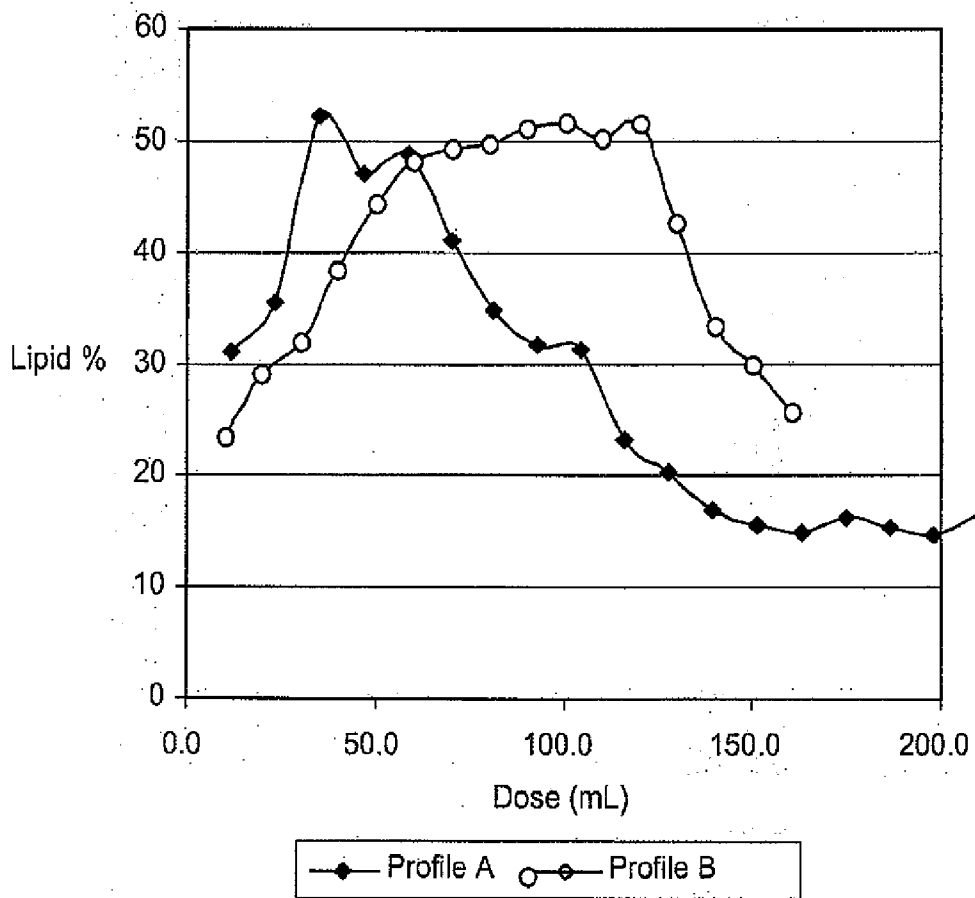


FIG. 21

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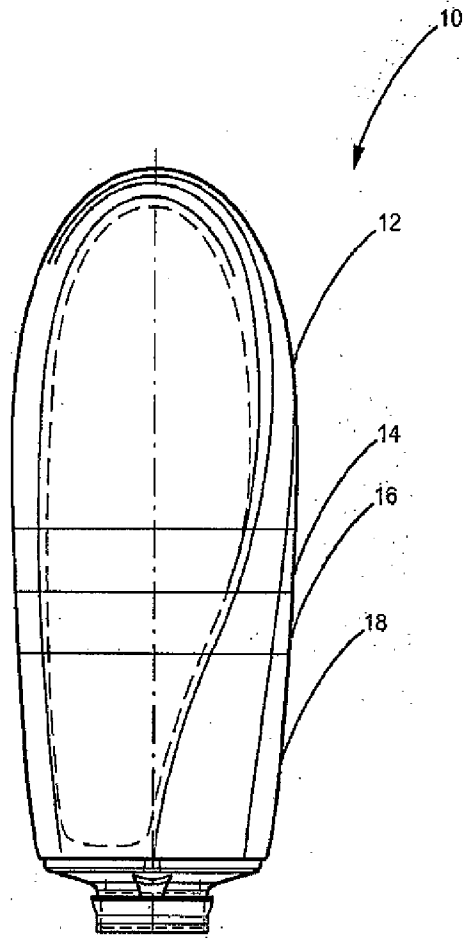
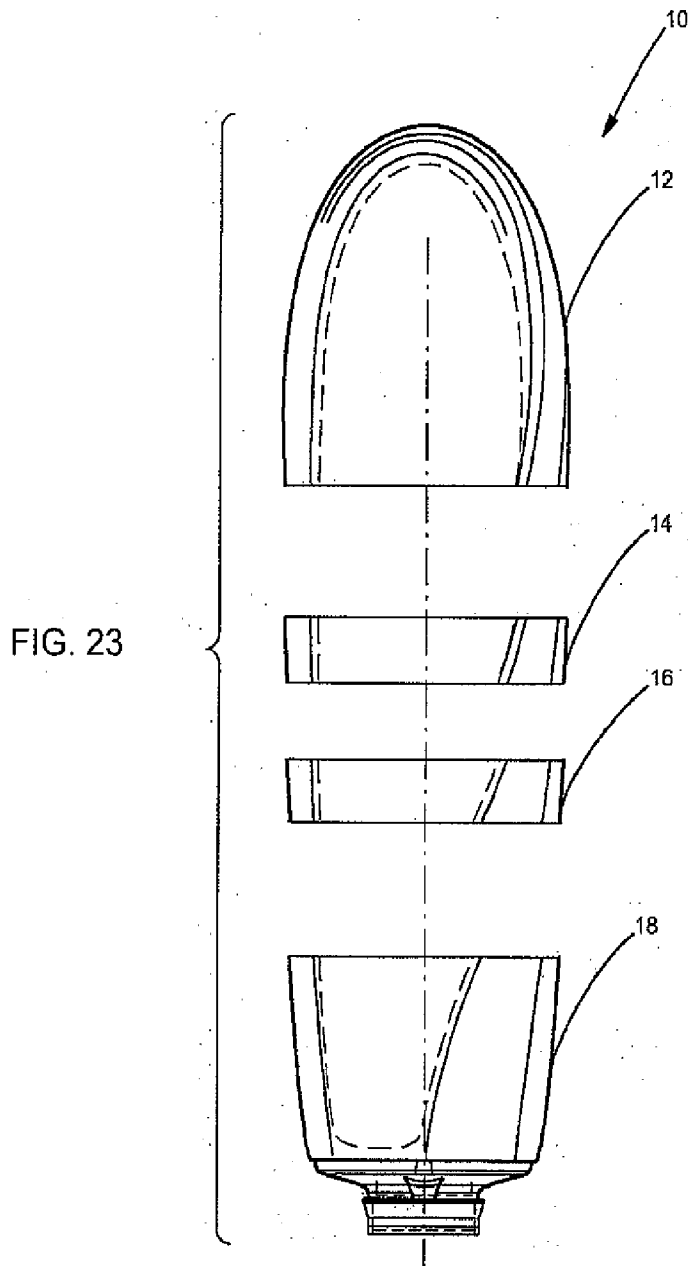


FIG. 22



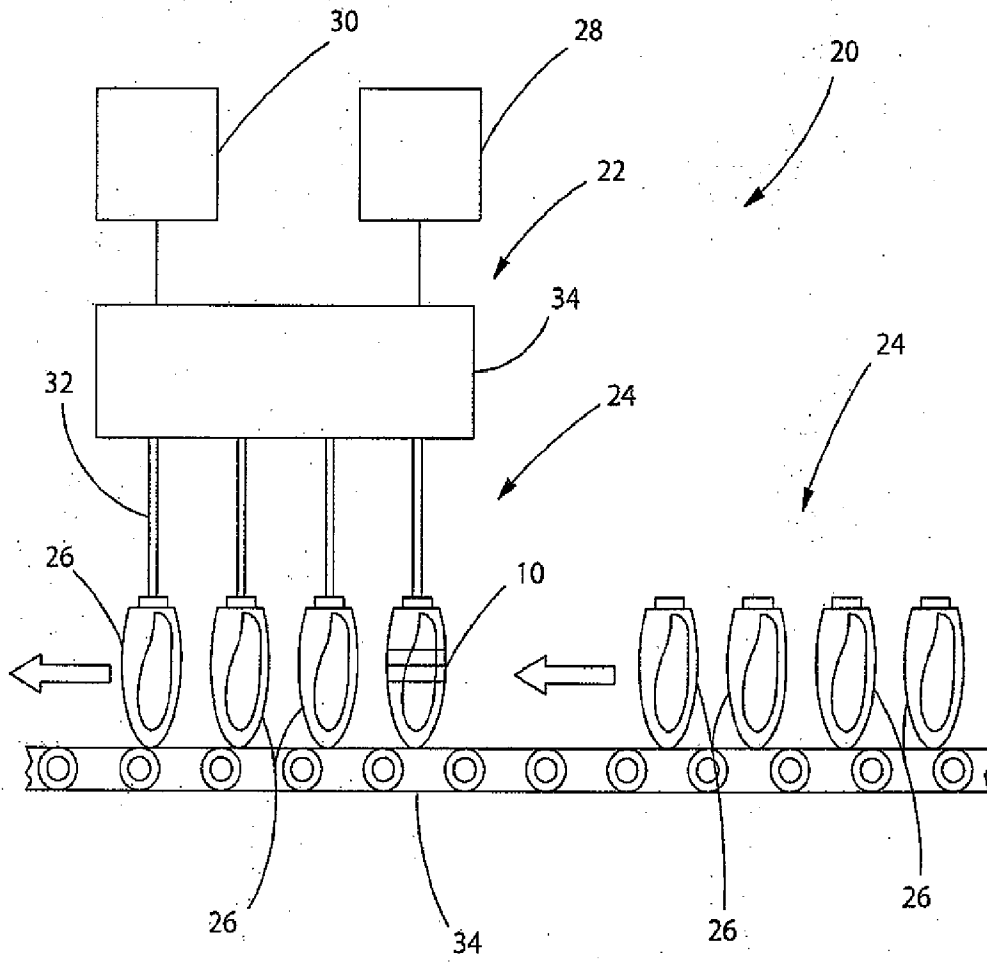


FIG. 24