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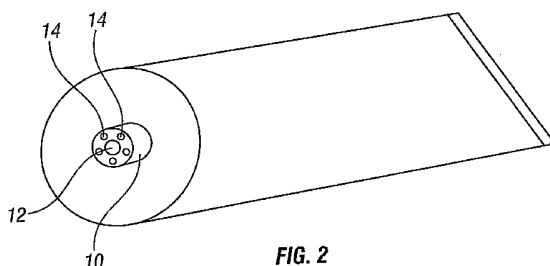


FIG. 2

(57) **Abstract:** The invention relates to a method of treating acne by the topical administration of an acne active ingredient in the presence of a) an anhydrous composition comprising a component that in the presence of water generates heat, and b) water. The invention also relates to an acne treatment kit comprising a first composition which is anhydrous and comprises a component that in the presence of water generates heat on the skin to which it is applied and a second composition which comprises an aqueous carrier, at least one of said compositions comprising an acne active ingredient, said compositions being stored in isolation from each other and being capable of generating heat when they are combined.

WO 2009/087354 A2

Skincare Treatment

The present invention relates to a method of treating acne, to an acne treatment kit, to compositions and kits useful in such methods and to
5 processes to prepare said composition and/or kits.

Acne vulgaris (acne) is a chronic inflammatory condition of the pilosebaceous units of the skin, which is particularly prevalent in adolescents. The condition generally causes the formation, on the skin, of comedones, red papules,
10 pustules and sometimes cysts. This is unsightly and furthermore, if untreated, acne can lead to scarring of the skin. The major causes of acne are thought to be an increase in sebum production, an increased presence of *Propionibacterium acne* (*P. acne*), blockage of the pilosebaceous duct and the production of inflammation.

15 Remedies for the topical treatment of acne generally provide for the application to the affected area of a skincare composition comprising at least one ingredient effective to treat acne. Such actives include the classes of topical retinoids, antibiotics, anti-bacterials and keratolytic agents, for example
20 tretinoin, adapalene, tazarotene, clindamycin, erythromycin, azelaic acid, benzoyl peroxide and salicylic acid.

It has now been found that an improved acne treatment may be achieved by the topical administration of an acne active ingredient in the presence of
25 a component that generates heat on the skin.

It has been found that the above treatment provides improved efficacy in the topical treatment of acne. For example, factors including improved sebum removal and improved pore cleansing may lead to a reduction in the number
30 and intensity of acne lesions.

Accordingly, the present invention provides a method of treating acne comprising the topical administration of an acne active ingredient in the presence of

- a) an anhydrous composition comprising a component that in the presence of water generates heat on the skin, and
- b) water.

5 In another aspect the present invention also provides an acne treatment kit comprising a first composition which is anhydrous and comprises a component that in the presence of water generates heat and a second composition which comprises an aqueous carrier, at least one of said compositions comprising an acne active ingredient, said compositions being
10 stored in isolation from each other and being capable of generating heat when they are combined.

In a yet further aspect the present invention provides a skincare formulation obtained by mixing on, or prior to application to, the skin comprising

- 15
- a) a first composition which is anhydrous and comprises a component that in the presence of water generates heat;
 - b) a second composition which comprises an aqueous carrier; and
 - c) at least one acne active ingredient.

20 In still a further aspect the present invention provides an anhydrous composition for the treatment of acne comprising an acne active ingredient, a component that in the presence of water generates heat and a carrier therefor.

25 The invention also provides an acne treatment package for dispensing a first and a second composition onto the skin, said first composition being anhydrous and comprising a component that in the presence of water generates heat and said second composition comprising an aqueous component, at least one of said compositions comprising an acne active
30 ingredient, wherein said package comprises a first chamber and a second chamber, each of said first and second chambers having an outlet, wherein said first composition is stored in said first chamber and said second composition is stored in said second chamber, said compositions being stored in isolation from each other and the package being arranged such that said

first and second compositions are combined after passing through each respective outlet.

5 The invention also provides a process of dispensing an acne treatment onto the skin comprising the application to the skin of a first composition which is anhydrous and comprises a component that in the presence of water generates heat, and a second composition which comprises an aqueous carrier, at least one of said compositions comprising an acne active ingredient, and mixing said compositions to generate heat on the skin.

10

The invention also provides a process to prepare an acne treatment kit comprising inserting a first composition which is anhydrous and comprises a component that in the presence of water generates heat into a first chamber of a multi-chambered package and inserting a second composition which
15 comprises an aqueous carrier into a second chamber of said package, at least one of said compositions comprising an acne active ingredient, and providing means for combining said compositions on, or prior to application to, the skin.

20 Where reference is made herein to an anhydrous composition, this means a composition which is substantially free of water; for example, it will contain less than 2% by weight water preferably less than 1% by weight water and most preferably less than 0.1% by weight water.

In a method according to the invention, an acne active ingredient is applied to
25 the skin in the presence of an anhydrous composition comprising a component that in the presence of water generates heat and water. The heat is generated on the skin and is useful to raise the temperature on the surface of the skin. The amount of heat-generating component present in the anhydrous composition is a level that the heat generated by the combination
30 of the anhydrous composition with the water is acceptable on the skin of a user and does not burn the skin.

In accordance with the present invention, the anhydrous composition may be applied to the skin and water applied thereto. The water may be applied

before, at the same time as, or after the application of the anhydrous composition. Preferably the anhydrous composition and water are combined by rubbing the ingredients together. In this way the heat generating component is most effectively combined with water to provide a heating effect
5 on the skin.

The water may be obtained from any suitable source, for example a water tap. The water may also be provided in an aqueous composition which may include one or more additional ingredients, especially skincare ingredients.

10 There may be sufficient water already present on the skin to produce a suitable heating effect if the anhydrous composition is rubbed into the skin with sufficient vigour.

Preferably, the aqueous composition forms part of a package in combination
15 with the anhydrous composition, which allows a measured amount of water to be applied to the skin thus allowing more control of the heating effect.

In one embodiment, the administration of the anhydrous composition and the aqueous composition on the skin is substantially simultaneous. The
20 anhydrous composition and aqueous composition may be combined just prior to application to the skin or they may be combined on the skin. For example, the anhydrous composition and aqueous composition may be dispensed from separate chambers within a package. The outlet of each chamber may allow the compositions to be applied directly onto the skin and
25 then combined by the user rubbing the compositions on the surface of the skin or the compositions may be combined as they pass through a dispensing nozzle before application to the skin.

A skincare formulation is provided when said anhydrous composition is
30 combined with water. Heat is generated on the skin which enhances the effect of the acne active ingredient. The skincare formulation may be left on the skin in which case the heat generated will gradually subside. Preferably the composition is rinsed off the skin, leaving a therapeutically effective amount of the acne active ingredient on the skin.

The acne active ingredient may be present separate from the anhydrous composition or the aqueous composition, it may be present in either the anhydrous and aqueous compositions or it may be present in both the anhydrous and aqueous compositions.

The acne active ingredient may be selected from any class of materials that are effective to treat acne, including topical retinoids, antibiotics, anti-microbials, anti-bacterials, anti-inflammatory agents and keratolytic agents, for example tretinoin, adapalene, tazarotene, clindamycin, erythromycin, azelaic acid, benzoyl peroxide, hydrogen peroxide and salicylic acid. If desired two or more acne active ingredients may be employed. The active ingredients may be present in the same or in different compositions.

The active ingredient is present in the formulation in a therapeutically effective amount, as generally known in the art. For most active ingredients, a range from 0.001% to 10% by weight, especially from 0.1% to 10% by weight, could be expected. Thus, generally each composition may comprise the above recited amount of acne active ingredient. Preferably, an acne active ingredient is present in an amount of 0.1% to 5% by weight of the anhydrous composition. Further preferably, an acne active ingredient is present in an amount of 0.1% to 5% by weight of the aqueous composition. However, it may be a benefit to reduce the total amount of any one active in the anhydrous or aqueous compositions, or to separate a plurality of actives, by including at least one acne active ingredient in both compositions. Thus, in a preferred embodiment, an acne active ingredient is present in an amount from 0.1% to 5% by weight of both aqueous and anhydrous compositions.

In one embodiment, said acne active ingredient is a keratolytic agent such as salicylic acid. Salicylic acid is preferably incorporated into the composition according to the invention as the free acid. However, the pH of the composition may, and generally will, be such that the salicylic acid exists in the composition in dissociated form. As the composition may well contain cationic counterions, the salicylic acid may then be thought of as being

present in salt form. Alternatively, the salicylic acid may be incorporated into the composition in salt form, eg as a salt with a Group I metal, such as sodium salicylate. As used herein, unless the context requires otherwise, any and all references to salicylic acid should be taken to encompass references to the acid and to dissociated forms and salts thereof.

The total concentration of salicylic acid in the formulation according to the invention, ie the combined anhydrous and aqueous compositions, is preferably at least 0.1% by weight, more preferably at least 0.5% by weight, most preferably at least 1.0% and especially at least 1.5% by weight. The concentration of salicylic acid is preferably less than 10% by weight, more preferably less than 6% by weight, and most preferably less than 4% by weight. Conveniently, the total concentration of salicylic acid may fall in the range 0.1% to 10% by weight, preferably 0.5% to 10% by weight, more preferably 1.0% to 6%, and most preferably 1.5% to 4.0% by weight. A particularly preferred total concentrations of salicylic acid is approximately 1.5-2% by weight of the composition.

In one embodiment, said acne active ingredient, preferably salicylic acid, is present in the anhydrous and aqueous compositions. The amount of acne active ingredient may be different in each composition. However, preferably, the aqueous composition comprises from 0.5% to 4% by weight, more preferably 1% to 3% by weight, acne active ingredient. Further preferably, the anhydrous composition comprises from 0.5% to 4% by weight, more preferably 1% to 3% by weight, acne active ingredient.

In accordance with the invention, any pharmaceutically acceptable component that generates heat in the presence of water may be used. Preferred examples are selected from the group of materials that generate heat within the classes of zeolites (aluminosilicates); metal halides, sulphates, carbonates and oxides; and polyhydric alcohols. Preferred classes of materials include zeolites and bivalent metal halides. These materials are well known to those skilled in the art. Examples of bivalent metal halides and oxides may include

magnesium chloride, iron chloride, zinc chloride, magnesium oxide, calcium oxide, magnesium sulphate and calcium chloride.

Such heat generating materials will suitably be present in the anhydrous composition in an amount to heat the skin to facilitate opening and cleansing of the pores. For example, such materials may be used in an amount of up to 70% by weight of the anhydrous composition, for example, from 1% to 70% by weight, preferably from 1% to 40% by weight, more preferably from 1% to 25% by weight and most preferably from 1% to 15% by weight.

10

The person skilled in the art will appreciate that the heat generated must be less than that which will cause heat damage to the skin. Preferably the temperature of the skin is raised by no more than 50°C. In order to be effective, preferably, the temperature of the skin is raised by at least 2°C, more preferably at least 10°C. Conveniently, the temperature of the skin may be raised to a temperature in the range 4 °C to 70 °C, preferably 4°C to 15°C

15

Preferably, the component that in the presence of water generates heat comprises a bivalent metal halide, further preferably a metal halide selected from magnesium chloride, iron chloride, zinc chloride and calcium chloride, most preferably magnesium chloride.

20

In one embodiment of the invention, the anhydrous composition comprises from 5% to 60% by weight, preferably from 10% to 50% by weight, more preferably from 12% to 40% by weight and most preferably from 15% to 35% by weight of said water-activatable, heat-generating component.

25

In accordance with the invention, the anhydrous composition comprises an anhydrous carrier. Conveniently, this may be an oily material. A physiologically effective oil useful in accordance with the present invention may be any cosmetically and/or dermatologically acceptable synthetic or natural oil known to the person skilled in the art. Such oils may also provide emollient properties on the skin, for example to maintain the soft, smooth and pliable appearance of the skin. Suitable ingredients include hydrocarbons,

30

silicone oils, triglycerides, waxes, fatty acids, fatty acid alcohols and esters thereof, mineral oils, vegetable oils and hydrogenated vegetable oils, lanolin or mixtures thereof. Examples of hydrocarbons include paraffins (for example paraffinum liquidum and white soft paraffin), petrolatum, hydrogenated
5 polyisobutene, alkyl benzoates, isohexadecane, isododecane, isononyl isonanoate, diisopropylcyclohexane; examples of silicone oils include dimethicone, cyclomethicone or cetyldimethicone; examples of triglycerides include natural triglycerides and synthetic or semi-synthetic triglycerides; examples of waxes include vegetable waxes such as carnauba wax, animal
10 waxes such as beeswax, and mineral waxes such as paraffin wax, ozokerite; examples of esters of fatty acids or alcohols include isopropyl palmitate, isopropyl myristate, dioctylmaleate, glyceryl oleate and cetostearyl isononanoate, octyl palmitate; examples of mineral oils include Vaseline oil; examples of vegetable oils include jojoba oil, soy bean oil, coconut oil,
15 sunflower seed oil, apricot kernel oil, shea butter, avocado oil and examples of hydrogenated vegetable oils include hydrogenated palm oil.

Such materials may be used in an amount greater than 30% by weight, more preferably greater than 35% by weight, advantageously greater than 40% by
20 weight and most preferably greater than 45% by weight of the composition. The carrier generally provides the largest component by weight of the anhydrous composition. Preferably, the anhydrous composition comprises from 30% to 99% by weight, preferably from 35% to 95% by weight, more preferably from 40% to 90% by weight and most preferably from 50% to 85%
25 by weight of said carrier.

In one embodiment, the anhydrous carrier comprises a mineral oil. Preferably, the mineral oil is blended with a styrene copolymer, for example a hydrogenated alkylene-styrene copolymer, more preferably a hydrogenated
30 butylene/ethylene/styrene copolymer or a hydrogenated ethylene/propylene/styrene copolymer or a mixture thereof. A particularly preferred source of a mineral oil/styrene copolymer blend is available under the tradename Versagel from Penreco, 138 Petrolia Karns City USA.

Preferably, mineral oil is combined with a hydrogenated alkylene-styrene copolymer/mineral oil blend.

5 In preferred compositions which comprise mineral oil, the total mineral oil is preferably present in an amount from 50% to 85% by weight, more preferably from 60% to 80% by weight, of the anhydrous composition; conveniently this may be a blend comprising mineral oil in an amount from 25% to 60% by weight (more preferably from 35% to 50% by weight) and a mineral oil/styrene copolymer blend in an amount from 20% to 40% by weight (more
10 preferably from 24% to 32% by weight).

In another embodiment, the anhydrous composition comprises a surfactant. This forms a particularly preferred aspect of the present invention as it provides a composition with advantageous viscosity and skin-feel properties.
15 For example, it may provide a less oily feel to the composition so that it is more pleasant to apply and retain on the skin. For example, a greasy and/or oily and/or sticky feel on the skin may be reduced. In particular, the inclusion of a surfactant in a composition where the carrier is a hydrocarbon (such as mineral oil) improves the aesthetic feel of the composition on the skin. In this
20 way, it has been found that less expensive carriers may be employed in the anhydrous composition. Furthermore, the anhydrous composition has good viscosity properties as it is not too viscous to apply and does not run off the skin when applied thereto. A suitable viscosity is that of a thickened liquid such that it is thicker than water and preferably remains in the area to which it
25 is applied, even when the user moves or applies it to a non-horizontal skin surface. It is a preferred feature of the invention that the compositions have a viscosity which allow them to be dispensed conveniently from a package, especially through a dispensing nozzle. The viscosity range values of such compositions will be known to those skilled in the art. The inclusion of at least
30 one surfactant may provide that it may not be necessary to include a thickening component in the composition. In one embodiment, the anhydrous composition comprises a surfactant and does not include a thickening component.

The surfactant may be an anionic, non-ionic, cationic and zwitterionic/amphoteric surfactant. Any conventionally used pharmaceutically and cosmetically acceptable surfactant may be used and these will be known to the person skilled in the art. Examples of non-ionic surfactants include the class of ethoxylated fatty alcohols and other surfactants such as oleth-5, PEG-5 cocamide, polysorbate 20, PEG-40 hydrogenated castor oil, alkyl poly(ethylene oxide), copolymers of poly(ethylene oxide) and poly(propylene oxide) (commercially called Poloxamers or Poloxamines), alkyl polyglucosides, including: octyl glucoside, decyl maltoside, fatty alcohols, cetyl alcohol, oleyl alcohol; examples of anionic surfactants includes the class of alkyl ether sulphates, such as sodium lauryl sulphate, sodium laureth sulphate, sodium dodecyl sulfate, ammonium lauryl sulfate, ammonium laureth sulphate, sodium C12-15 pareth sulphate and disodium laureth sulfosuccinate, soaps or fatty acid salts ; examples of cationic surfactants include cationic modified guar, alkyltrimethylammonium salts, for example cetrimonium chloride, cetyl trimethylammonium bromide, cetylpyridinium chloride, polyethoxylated tallow amine, benzalkonium chloride, benzethonium chloride and behentrimonium chloride; examples of amphoteric surfactants include the class of alkylamido alkyl amines and dodecyl betaine, dodecyl dimethylamine oxide, cocamidopropyl betaine, cocamidopropyl hydroxysultaine, sodium lauroamphoacetate, cocoamphoglycinate or sodium cocoamphoacetate. A further preferred group of classes of surfactants are alkyl sulphates, alkyl ether sulphates, alpha-olefin sulphates, alkylsarcosinates and aryl-sulphonated derivatives thereof.

Preferably, the surfactant comprises an anionic surfactant, optionally in combination with other surfactants. Most preferably, the surfactant comprises an alkali metal sulphate, such as sodium lauryl sulphate and/or sodium dodecyl sulphate.

Preferably, when present, the anhydrous composition comprises from 1-20% by weight surfactant, further preferably from 1% to 10% by weight, more preferably from 3% to 15% by weight and most preferably from 4% to 10% by weight surfactant.

In one embodiment, the present invention provides an anhydrous composition comprising

- (a) 1% to 5% by weight salicylic acid;
- 5 (b) 10% to 35% by weight magnesium chloride;
- (c) 4% to 10% by weight surfactant; and
- (d) 50% to 85% by weight carrier.

Further preferably, the anhydrous composition consists essentially of the
10 above ingredients.

In one embodiment of the present invention, the aqueous composition is a cleansing composition comprising a surfactant. The surfactant may be an anionic, non-ionic, cationic and zwitterionic/amphoteric surfactant. Any
15 conventionally used pharmaceutically and cosmetically acceptable surfactant may be used and these will be known to the person skilled in the art. Particular surfactants may be as described above with respect to the anhydrous composition. Preferably, the surfactant comprises an anionic surfactant and/or a non-ionic surfactant. Preferred materials include lauryl or
20 laureth sulphates (such as sodium or triethanolamine lauryl/laureth sulphates) and polypropyleneglycols, polyethylene glycols and derivatives thereof.

In preferred compositions, it is desired that the total surfactant concentration in the aqueous and anhydrous compositions when combined to provide the
25 formulation, is sufficient such that when rubbed into the skin, a foam is produced which can be rinsed off the skin.

The aqueous and anhydrous compositions may also include other skincare ingredients as desired, for example emollients, humectants, film formers,
30 cooling agents, soothing agents, anti-inflammatories.

In particular, the anhydrous and aqueous compositions may also comprise thickening agents which increase the viscosity of the composition. Examples include polyethylene glycols; polyoxyethylene cetyl ethers; Acrylates/Vinyl

Isodecanoate crosspolymer, polyamide resins such as Sylvaclear (tradename), lanolin, stearyl alcohol and salt.

In one embodiment, the present invention provides an aqueous composition
5 comprising

- (a) 1% to 5% by weight salicylic acid;
- (b) 5% to 85% by weight surfactant; and
- (c) 10% to 94% by weight water.

10 Further preferably, the aqueous composition consists essentially of the above ingredients.

Preferably, when present, the anhydrous and/or aqueous compositions
comprise from 1-20% by weight thickener, more preferably from 2% to 15% by
15 weight and most preferably from 3% to 10% by weight thickener.

The aqueous and anhydrous compositions provided in accordance with the
present invention are suitably in the form of a liquid or a gel, preferably as a
viscous liquid.

20

In accordance with the present invention, the anhydrous and aqueous
compositions may comprise other conventional ingredients, such as anti-
microbial agents, sequestering agents, colouring agents and perfumes. Such
ingredients and the amounts in which they are incorporated in the composition
25 are within the knowledge of those skilled in the art.

The present invention also provides an acne treatment package for storing
and dispensing the above described aqueous and anhydrous compositions
onto the skin. The package comprises a first chamber and a second chamber,
30 each chamber having an outlet thereto, wherein said anhydrous composition
is stored in said first chamber and said aqueous composition is stored in said
second chamber, said compositions being stored in isolation from each other
and being arranged to be combined after passing through said respective

outlets onto the skin. On combination of the compositions, heat is generated, effective to raise the temperature of the skin.

In expelling a portion of the contents of the package, each composition
5 passes through the outlet of the chamber in which it is stored. The outlets may be adjacent so that on expelling the compositions from the package at the same time, they may be combined after they pass through the outlets onto the skin. It may be desired however to expel the compositions separately, for example to apply one composition and then target the second composition in
10 the area of the first composition. In this case it is not necessary that the outlets of each chamber are near to each other. Although a heating effect is obtained as soon as the water comes into contact with the component that generates heat on contact with water, it is preferred to mix the compositions by rubbing them into the skin.

15 In one embodiment, the package further comprises a dispensing nozzle through which the combined compositions are dispensed onto the skin. The aqueous and anhydrous compositions may be combined in the dispensing nozzle or a chamber leading thereto and then targeted onto the affected area
20 of the skin.

In one embodiment the package comprises a receptacle partitioned into first and second chambers. Preferably, the package comprises a dispensing nozzle in which the aqueous and anhydrous compositions may be combined
25 before being expelled onto the skin.

In another embodiment the package comprises a tube comprising an anhydrous or aqueous composition and an inner tube comprising the other of said anhydrous or aqueous composition. Suitably, the inner tube is
30 encompassed within an outer tube which forms the packaging.

Preferably, the package is squeezable to expel said anhydrous or aqueous compositions.

It will be appreciated that a method according to the invention, including a method of treating acne comprising the topical administration of an acne active ingredient in the presence of a component that in the presence of water generates heat, may be a therapeutic method, but will often be a primarily
5 cosmetic method, the objective of which is to reduce or eliminate externally visible, and often unsightly, symptoms of acne.

The invention will now be described in more detail, by way of illustration only, with reference to the accompanying drawings.

10

In the drawings:

Figure 1 shows a side view of a package comprising an inner tube containing a first composition located within a clear outer tube containing a second composition;

15 Figure 2 shows a perspective view of one end of a tube comprising a first dispensing nozzle;

Figure 3 shows an end view of a second dispensing nozzle;

Figure 4 shows a sectional view of a partitioned package comprising first and second chambers;

20 Figure 5 shows an expanded perspective view of the dispensing nozzle from a partitioned package.

Referring firstly to Figure 1, an acne treatment package (2) for dispensing first and second compositions onto the skin comprises an outer tube (4) which
25 provides a first chamber and an inner tube (6) which provides a second chamber, the contents of the first chamber being isolated from the second chamber. The outer tube has a cap (8).

An aqueous composition which comprises an acne active ingredient is stored
30 in said first (outer) chamber and an anhydrous composition which comprises an acne active ingredient and a component that in the presence of water generates heat on the skin is stored in said second (inner) chamber.

In another embodiment, the anhydrous composition is present in the outer tube and the aqueous composition is present in the inner tube.

5 In a further embodiment, the acne active ingredient is present in either one of the anhydrous or aqueous compositions.

In a further embodiment, at least one surfactant is present in either one of or both of the anhydrous and aqueous compositions.

10 Referring to Figure 2, the package comprises a neck which forms a dispensing nozzle (10). The inner tube has an outlet leading into a central channel (12) of the dispensing nozzle. The outer tube has an outlet leading to a plurality of openings (14) around the periphery of the dispensing nozzle.

15 In use, the dispensing nozzle (10) is placed on or near the affected area of the skin and the outer and inner tubes squeezed simultaneously. The anhydrous composition is expelled through the central channel (12) and the aqueous composition is expelled from the plurality of openings (14). As the compositions are expelled from the package they are combined as they pass onto the skin. The combined compositions are rubbed together into the skin
20 which causes heat to be generated. The combined formulation is then rinsed from the skin.

Figure 3 shows an embodiment where the central passage (12) is enlarged towards the periphery of the dispensing nozzle and allows a greater amount of
25 the composition in the inner tube to be expelled at a given time in relation to the amount of composition expelled from the openings (14) in the outer tube.

Figure 4 shows a section view of a partitioned package (16) providing first (18) and second (20) chambers. The anhydrous composition is stored in the first
30 chamber (18). The aqueous composition is stored in the second chamber (20).

Figure 5 shows a perspective view of one end of the partitioned package (16) which is in the form of a tube. The package comprises a neck which forms a

dispensing nozzle (22). The dispensing nozzle is divided down the middle to form two semi-circular channels. A first channel connects the first chamber (18) with a dispensing aperture (24). A second channel connects the second chamber (20) with a dispensing aperture (26).

5

When it is desired to apply the combined compositions to the skin, the dispensing nozzle (10) is placed on or near the affected area of the skin and the tube (16) squeezed. The anhydrous composition is expelled from the aperture (24) and the aqueous composition is expelled from the aperture (26).

10 As the compositions are expelled from the package they are combined as they pass onto the skin. The combined compositions are rubbed together into the skin which causes heat to be generated. The combined formulation is then rinsed from the skin.

15 In the following examples, there are described several preferred embodiments to illustrate the invention. However, it is to be understood that the invention is not to be limited to the specific embodiments.

In the examples, the ingredients are available as follows:

20 Carrier¹ is a blend of mineral oil and ethylene/propylene/styrene copolymer and butylene/ethylene/styrene copolymer is available from Penreco under the trade name Versagel M -1600; Carrier² is a blend of mineral oil and ethylene/propylene/styrene copolymer and butylene/ethylene/styrene copolymer and is available from Penreco under the trade name Versagel R-500; Thickener¹

25 is a combination of Glyceryl Dibehenate, Tribehenin and Glyceryl Behenate and is available from Gattefosse under the tradename Compritol ATO 888; Thickener² is polyoxyethylene cetyl ether available under the tradename Brij 56; Acrylates/Vinyl Isodecanoate crosspolymer is available from 3V under the tradename Stabylen-30; The polyamide resin is available from Arizona

30 Chemical under the tradename Sylvaclear AF1900V; Triethanolamine laureth sulphate (TEA-LS) is available under the tradename Sunform-T7; cocamidopropyl betaine is available under the trade name Incronam 30; PEG-150 is available under the tradename Crothix liquid; PEG-150 Pentaerythrityl Tetrastearate is available from Crothix;

- Any one of the heating compositions illustrated below may be combined with any of the aqueous compositions illustrated below. The compositions are
- 5 rubbed together on the skin and after a desired period may be rinsed off.

Heating Compositions

- 10 The ingredients listed in each example below were combined by mixing according to conventional methods.

15 **Examples 1- 4**

Materials	Examples			
	1	2	3	4
Carrier ¹	38.5%	38.5%	-	-
Carrier ²	-	-	38.5%	38.5%
Light Mineral oil	45%	45%	45%	45%
Salicylic acid	1.5%	1.5%	1.5%	1.5%
MgCl ₂	15%	-	15%	-
Zeolite	-	15%	-	15%

Examples 5-10

Materials	Examples					
	5	6	7	8	9	10
Carrier ²	38.5%	25%	15.5%	15.5%	-	13%
Light Mineral oil	25%	31.8%	60%	60%	33.5%	35%
Salicylic acid	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%
Butylene glycol	20%	26.7%	-	-	30%	15.5%
Thickener ¹	-	-	8%	8%	-	-
MgCl ₂	15%	15%	-	15%	-	-
Zeolite	-	-	15%	-	15%	15%
PEG-8	-	-	-	-	10%	10%
Thickener ²	-	-	-	-	10%	10%

5 Examples 11-14

Materials	Examples			
	11	12	13	14
Carrier ²	13.5%	13.5%	7%	-
Light Mineral oil	-	-	68.5%	60.5%
Salicylic acid	1.5%	1.5%	1.5%	1.5%
Butylene glycol	50%	45%		-
Thickener ¹	-	-	8%	8%
Zeolite	15%	30%	15%	30%
PEG-8	10%	5%	-	-
Brij 56	10%	5%	-	-

Examples 15-17

Materials	Examples		
	15	16	17
Salicylic acid	1.5%	1.5%	1.5%
Butylene glycol	40%	26%	25%
Glycerine	26%	40%	40%
Acrylates/Vinyl Isodecanoate crosspolymer	-	-	1%
Zeolite	25%	25%	25%
PEG-8	7.5%	7.5%	7.5%

5

Examples 18-20

Materials	Examples		
	18	19	20
Salicylic acid	1.5%	1.5%	1.5%
Butylene glycol	38.5%	-	-
Light mineral oil	-	59.5%	45.5%
Carrier ¹	-	-	15%
MgCl ₂	35%	35%	35%
PEG-8	5%	-	-
polyamide resin	5%	-	-
Polypropylene glycol (PPG) -14	15%	-	-
Thickener ¹	-	4%	3%

10

Examples 21-25

Materials	Examples				
	21	22	23	24	25
Salicylic acid	1.5%	1.5%	1.5%	1.5%	1.5%
Carrier ¹	27.5%	15%	15%	15%	15%
Thickener ¹	6%	2.7%	8.2%	3%	6%
Mineral oil	40%	45%	40%	45%	42.5%
MgCl ₂	25%	35%	35%	35%	35%
Fragrance	-	0.3%	0.3%	-	-

Examples 26-28

5

Materials	26	27	28
Salicylic acid	1.5%	1.5%	1.5%
Carrier ¹	15%	10%	10%
Thickener ¹	-	2.5%	-
Mineral oil	43.5%	48.5%	43.5%
Sodium Dodecyl Sulfate	5%	2.5%	10%
MgCl ₂	35%	35%	35%

10 **Examples 29-30**

Materials	29	30
Salicylic acid	2%	2%
Carrier ¹	15%	30%
Mineral oil	48%	43%
Sodium Dodecyl Sulfate	5%	5%
MgCl ₂	30%	20%

Aqueous Cleansing Compositions

The ingredients listed in each example below were combined by mixing according to conventional methods.

5

Examples 31- 34

Materials	Examples			
	31	32	33	34
Water	27%	20%	25%	25%
Salicylic acid	1.5%	1.5%	1.5%	1.5%
Butylene glycol	15%	-	-	-
Polyamide resin	3%	-	-	-
Glycerol	-	25%	15%	15%
Ethanol	45%	45%	45%	45%
Menthol (L)	3.5%	-	3.5%	-
Menthol (D/L)	-	3.5%	-	3.5%
TEA – Laureth Sulphate	-	-	5%	5%
PEG – 8	5%	5%	5%	5%

Examples 35 - 40

5

Materials	Examples					
	35	36	37	38	39	40
Salicylic acid	2%	2%	2%	2%	2%	2%
Butylene glycol	35%	30%	20%	22%	-	35%
Glycerol	25%	20%	30%	30%	40%	25%
PEG-7 glyceryl cocoate	2.5%	2.5%	4%	3%	2%	2%
PEG-150 Pentaerythrityl Tetrastearate	5%	5%	4%	4%	10%	3%
PEG-8	2.5%	2.5%	4%	3%	2%	3%
polyamide resin	5%	15%	3%	-	-	-
PPG -14 butyl ether	-	-	10%	13%	13%	-
Water	13%	13%	13%	3%	21%	20%
Sodium Lauryl Sulphate (30 % in water)	10%	10%	10%	20%	10%	-
Cocamidopropyl Betaine	-	-	-	-	-	10%

10

15

Examples 41- 44

5

Materials	Examples			
	41	42	43	44
Salicylic acid	2%	2%	2%	2%
Butylene glycol	35%	35%	30%	30%
Glycerol	20%	20%	20%	20%
PEG-7 glyceryl cocoate	2%	2%	2%	2%
PEG-8	2%	2%	2%	2%
Hydrolysed milk protein	0.2%	0.2%	0.2%	0.2%
PPG -14 butyl ether	10%	10%	5%	6%
cocamidopropyl betaine	-	2.3%	2.9%	2.8%
Sodium Lauryl Sulphate (30 % in water)	7.5%	5.3%	6.7%	6.7%
Lanolin	-	-	1%	0.5%
Stearyl alcohol	-	-	2%	1.5%
Sodium Chloride	1%	1%	1%	1%
PEG - 150	-	-	3%	3%
Water	to 100%	to 100%	to 100%	to 100%

Examples 45-49

5

Materials	Examples				
	45	46	47	48	49
Butylene Glycol	30%	30%	30%	30%	30%
Glycerine	20%	20%	20%	20%	20%
PEG-7	1.5%	2%	2%	2.5%	2.5%
PEG-8	1.5%	2%	2%	2.5%	2.5%
PPG-14	6.5%	6.5%	6.5%	5%	5%
Lanolin	2%	2%	2%	2%	2%
Stearyl Alcohol	-	-	-	0.5%	1%
PEG-150	3.5%	2.5%	2.5%	3%	3%
Sodium lauryl sulphate	6.7%	6.7%	6.7%	6.1%	6.1%
cocamidopropyl betaine	2.8%	2.8%	2.8%	2.8%	2.8%
NaCl	1%	1%	1%	1%	1%
Salicylic Acid	2%	2%	2%	2%	2%
Hydrolysed Milk Protein	0.2%	0.2%	0.2%	0.2%	0.2%
Water	to 100%	to 100%	to 100%	to 100%	to 100%

Examples 50-54

Materials	Examples				
	50	51	52	53	54
Butylene Glycol	22.5	22.5	22.5	12.5	12.5
Glycerine	15	15	15	5	5
PEG-7	2.3	2.3	2.3	2.5	2.5
PEG-8	2.3	2.3	2.3	1.5	1.5
PPG-14	3.8	3.8	3.8	3.8	3.8
Lanolin	0.4	0.4	0.4	-	-
Protanal LF 10/60	0.4	-	-	-	-
Carrageenan	-	0.4	1.5	-	-
Carbopol polymer	-	-	-	1	3.8
Crothix Solid	-	-	-	1.5	-
Sodium lauryl sulphate	6.5	6.5	6.5	5	2
Incronam	2.1	2.1	2.1	2.1	2.1
NaCl	0.4	0.4	0.4	0.8	0.8
Salicylic Acid	1.5	1.5	1.5	1.5	1.5
Hydrolysed Milk Protein	0.2	0.2	0.2	0.2	0.2
Colour	qs	qs	qs	qs	qs
Fragrance	qs	qs	qs	qs	qs
water	to 100%	to 100%	to 100%	to 100%	to 100%

5 Amounts are shown in g

Examples 55 - 56

Materials	Examples	
	55	56
Butylene Glycol:	6.0000	6.0000
Glycerine:	3.0000	3.0000
PEG-7	1.5000	1.5000
PEG-8	1.5000	1.5000
PPG-14	3.0000	3.0000
S.L.S	7.5000	6.3750
Arrowroot	3.0000	4.5000
Incronam	1.0500	1.0500
Water:	44.6250	44.2500
Sodium chloride	0.7500	0.7500
Salicylic Acid	1.5000	1.5000
Hydrolysed Milk Protein	1.5000	1.5000
Colour	qs	qs
Fragrance	qs	qs

5 Examples 57- 60

Materials	Examples			
	57	58	59	60
Sodium hydroxide (25 %)	0.86	0.86	0.34	0.8625
Carbopol CC polymer	3.75	3.75	-	11.2500
Glycerine	4.36	11.25	4.5	8.4375
PEG-7	1.125	1.125	13.5	0.8438
PEG-8	1.125	1.125	0.15	0.8438
S.L.S (27%)	7.5	-	1.13	22.5000
S.D.S solid	-	15	1.13	-
Cocamidopropyl betaine (30 %)	7.5	-	11.25	-
Water added	47.2	40.31	11.25	28.6875
Salicylic Acid	1.5	1.5	29.25	1.5000

Colour	0.0002	0.0002	1.5	0.0002
Fragrance	0.075	0.075	0.0002	0.0750

Examples 61-62

Materials	Examples	
	61	62 5
Glycerine:	2.25	2.25
Water:	43.67	43.67
NaCl	0.94	0.94
Salicylic Acid	1.5	1.5
Hydrolysed Milk Protein	0.15	¹⁰ 0.15
Colour	0.0003	0.0003
Fragrance	0.15	0.15
Sodium hydroxide @ 25 %	0.14	0.14
Plantacare 818 UP	6	6
Texapon NSO	20.25	¹⁵ -
Plantapon 611C	-	20.25

Examples 63 - 64

Materials	63	64
Salicylic Acid	2	2
Colour	qs	qs
Fragrance	qs	qs
Cocoglucoside (50%)	8	8
Glycerin	2.7	2.7
Salt (NaCl)		1.2
Sodium Laureth-2 Sulphate (27%)	52	67.7
Levomenthol	0.1	-
Hydrolysed milk protein	0.2	
Sodium chloride	1.1	
Water	to 100%	to 100%

5 Test Method**Skin Preparation:**

A sheet of vitro-skin was accurately cut using a guillotine into 10 equal pieces. Each of these pieces was then numbered and weighed before the addition of sebum. Sebum was added to the skin as a solid that could be rubbed across the whole of the skin surface (matte side) until the whole surface was covered (~0.2g). Each piece of skin was then weighed once more before being placed in the hydration chamber.

The hydration chamber was prepared by adding a mixture of Glycerine (44g) and DI water (256g) to the bottom of it. The skin was then placed on the contained shelves and allowed to stand, with the lid tightly in place for approximately 24 hours at ambient conditions in order to ensure a realistic level of vitro-skin hydration.

Cleansing Method

After 24 hours the lid was removed and cleansing tests were carried out on
5 the skin. For all tests, the vitro-skin was placed on a foam surface to mimic the non-solidity of skin.

For all samples, 5ml of DI water at room temperature was accurately syringed
onto the surface of the vitro-skin. This was then massaged into the skin using
a gloved finger with small circular movements for ten seconds. Once this was
10 done the test sample was applied and massaged into the skin.

After cleansing all skin samples were thoroughly rinsed until for a minimum of
30 seconds, or until all visible products had been removed (as would be the
case in a realistic situation).

After cleansing, the vitro-skin was left to dry on the shelves provided in the
15 hydration chamber.

After 24 hours the skin was then re-weighed providing the information that
was required to then calculate the percentage of sebum removed from each
piece of vitro-skin.

All testing carried out on vitro-skin was repeated 5 times for each variable.
20

The test samples were:

A : Water

B: Part 1 – Anhydrous composition comprising mineral oil, surfactant,
magnesium chloride and salicylic acid (2% w/w) as illustrated
25 herein.

Part 2 - Aqueous cleansing composition comprising surfactant and
salicylic acid (2% w/w) as illustrated herein

C: Aqueous cleansing composition comprising surfactant and salicylic acid
(2% w/w) as illustrated herein

The test results were as follows:

	Mass of Skin.	Mass of Skin + Sebum	Mass of Skin + Sebum After Cleansing	Mass of Sebum Removed	% Sebum Removed	Average	Standard Deviation	Confidence
A	0.601	0.798	0.705	0.093	47.2081	32.7214	12.5944	11.039280
	0.599	0.808	0.779	0.029	13.8756			
	0.590	0.794	0.735	0.059	28.9216			
	0.568	0.762	0.697	0.065	33.5052			
	0.561	0.768	0.685	0.083	40.0966			
B	0.581	0.782	0.668	0.114	56.7164	78.6322	5.29019	3.4561965
	0.563	0.771	0.619	0.152	73.0769			
	0.565	0.754	0.608	0.146	77.2487			
	0.604	0.800	0.629	0.171	87.2449			
	0.598	0.783	0.630	0.153	82.7027			
	0.463	0.661	0.515	0.146	73.7374			
	0.457	0.637	0.503	0.134	74.4444			
	0.444	0.626	0.479	0.147	80.7692			
	0.467	0.679	0.522	0.157	74.0566			
	0.455	0.641	0.484	0.157	84.4086			
C	0.617	0.830	0.704	0.126	59.1549	44.9166	13.0069	11.400818
	0.580	0.790	0.670	0.120	57.1429			
	0.560	0.751	0.669	0.082	42.9319			
	0.577	0.758	0.693	0.065	35.9116			
	0.552	0.749	0.691	0.058	29.4416			

5

10

15

Claims

1. A method of treating acne by the topical administration of an acne active ingredient in the presence of
 - 5 a) an anhydrous composition comprising a component that in the presence of water generates heat, and
 - b) water.
2. A method according to Claim 1, wherein the administration of the anhydrous composition and the aqueous composition is substantially simultaneous.
3. A method according to Claim 1 or Claim 2, wherein said acne active ingredient is present in said anhydrous composition.
4. A method according to any one of the preceding claims, wherein said acne active ingredient is present in said aqueous composition.
5. A method according to any one of the preceding claims, wherein the acne active ingredient is selected from keratolytic agents, preferably salicylic acid.
6. A method according to any one of the preceding claims, wherein the acne active ingredient is present in an amount of from 0.1% to 10% by weight of the combined anhydrous and aqueous compositions.
7. A method according to any one of the preceding claims, wherein the acne active ingredient is present in an amount of 0.1% to 5% by weight of the anhydrous composition.
8. A method according to any one of the preceding claims, wherein the acne active ingredient is present in an amount of 0.1% to 5% by weight of the aqueous composition.

9. A method according to any one of the preceding claims, wherein the component activatable by water to generate heat on the skin is selected from the group of zeolites and bivalent metal halides.

5 10. A method according to Claim 9, wherein the component activatable by water to generate heat on the skin is magnesium chloride.

11. A method according to Claim 9 or Claim 10, wherein said anhydrous composition comprises from 5% to 60% by weight of said component that
10 generates heat in the presence of water.

12. A method according to any one of the preceding claims, wherein the anhydrous composition comprises an anhydrous carrier.

15 13. A method according to Claim 12, wherein the anhydrous carrier comprises a hydrocarbon material.

14. A method according to Claim 13, wherein the anhydrous carrier comprises mineral oil.

20

15. A method according to any one of the preceding claims, wherein the anhydrous composition comprises a surfactant.

16. A method according to Claim 15, wherein the surfactant is selected
25 from alkyl sulphates, alkyl ether sulphates, alpha-olefin sulphates, alkylsarcosinates and aryl-sulphonated derivatives thereof.

17. A method according to Claim 16 wherein the surfactant is selected from sodium lauryl sulphate or sodium dodecyl sulphate.

30

18. A method according to any one of claims 15 to 17, wherein the anhydrous composition comprises from 1% to 10% by weight surfactant.

19. A method according to any one of the preceding claims, wherein the aqueous composition is a cleansing composition comprising a surfactant.

20. An acne treatment kit comprising a first composition which is anhydrous and comprises a component that in the presence of water generates heat on the skin to which it is applied and a second composition which comprises an aqueous carrier, at least one of said compositions comprising an acne active ingredient, said compositions being stored in isolation from each other and being capable of generating heat when they are combined.

21. A skincare formulation obtained by mixing on, or prior to application to, the skin comprising

- a) a first composition which is anhydrous and comprises a component that in the presence of water generates heat;
- b) a second composition which comprises an aqueous carrier; and
- c) at least one acne active ingredient.

22. An anhydrous composition for the treatment of acne comprising an acne active ingredient, a component that in the presence of water generates heat and a carrier therefor.

23. A composition according to Claim 22, wherein the carrier comprises a hydrocarbon, preferably a mineral oil.

24. A composition according to Claim 23, wherein said composition comprises a surfactant.

25. A composition according to Claim 24, wherein said surfactant is selected from alkyl sulphates and alkyl ether sulphates.

26. A composition according to claim 22 comprising

- (a) 1-5% by weight acne active ingredient;

- (b) 20-40% by weight component that in the presence of water generates heat;
- (c) 50-85% by weight carrier; and
- (d) 1-10% surfactant.

5

27. A composition according to any one of Claims 22 to 26 in the form of a thickened liquid which does not flow off the skin.

10

28. An acne treatment package for dispensing a first and a second composition onto the skin, said first composition being anhydrous and comprising a component that in the presence of water generates heat and said second composition comprising an aqueous component, at least one of said compositions comprising an acne active ingredient, wherein said package comprises a first chamber and a second chamber, each of said first and second chambers having an outlet, wherein said first composition is stored in said first chamber and said second composition is stored in said second chamber, said compositions being stored in isolation from each other and the package being arranged such that said compositions are combined after passing through said respective outlet.

20

29. A package according to claim 28, wherein said package further comprising a dispensing nozzle through which the combined compositions are dispensed onto the skin.

25

30. A package according to claim 28 or claim 29 comprising a receptacle partitioned into first and second chambers.

30

31. A package according to claim 28 or claim 29 comprising a tube comprising said first or said second composition and an inner tube comprising the other of said first or second composition.

32. A package according to any one of claims 28 to 31, wherein the package is squeezable to expel said first and second compositions.

33. A process to prepare an acne treatment kit comprising inserting a first composition which is anhydrous and comprises a component that in the presence of water generates heat into a first chamber of a multi-chambered package and inserting a second composition which comprises an aqueous carrier into a second chamber of said package, at least one of said compositions comprising an acne active ingredient, and providing means for combining said compositions on, or prior to application to, the skin.
34. A process of dispensing an acne treatment onto the skin comprising the application to the skin of a first composition which is anhydrous and comprises a component that in the presence of water generates heat, and a second composition which comprises an aqueous carrier, at least one of said compositions comprising an acne active ingredient and mixing said compositions to generate heat on the skin.
35. A method for reducing the oily feel on the skin of an anhydrous composition including a hydrocarbon carrier comprising the incorporation of a surfactant in said composition.

1/2

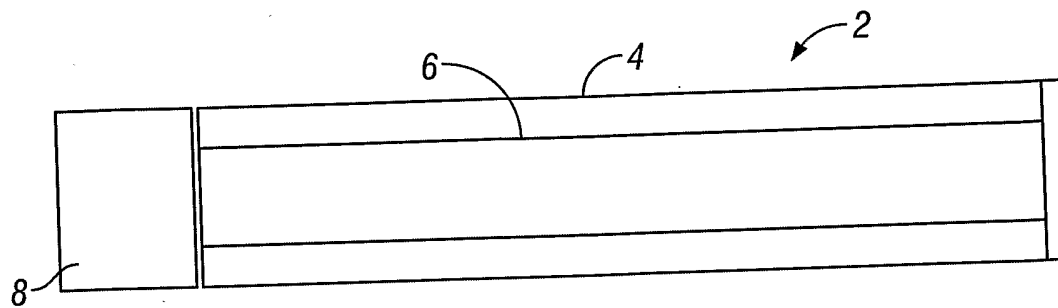


FIG. 1

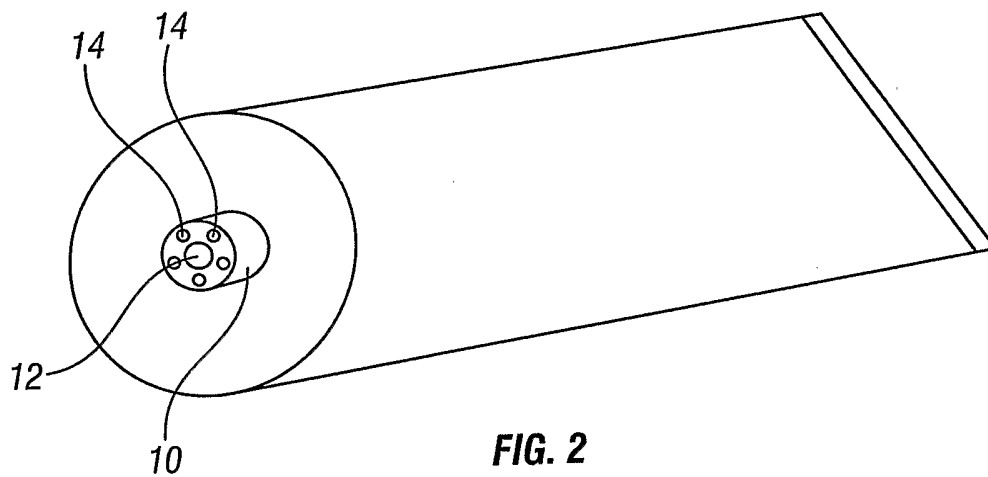


FIG. 2

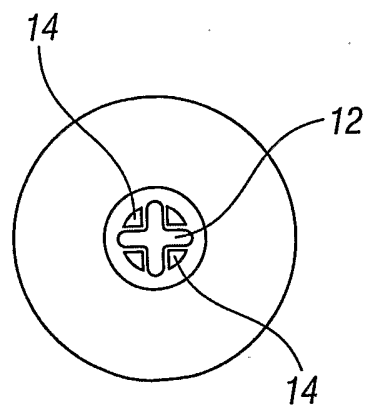


FIG. 3

2/2

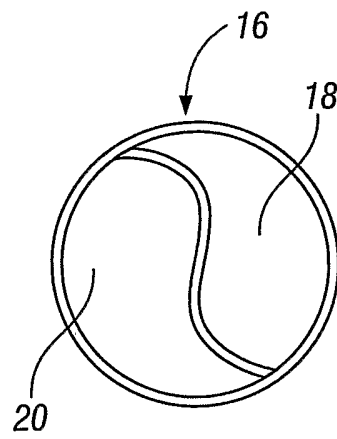


FIG. 4

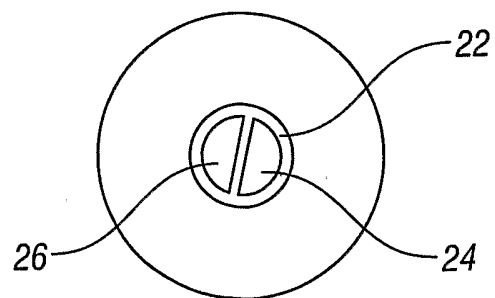


FIG. 5