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(54) Title: FOAMABLE TOPICAL COMPOSITION

(57) Abstract: A foamable composition for topical application, the composition comprising a water in oil emulsion.



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FOAMABLE TOPICAL COMPOSITION

FIELD OF THE INVENTION

The present invention relates to the field of chemical compositions, and
5 more specifically to a foamable composition for topical application, the
composition comprising a water in oil emulsion.

BACKGROUND OF THE INVENTION

Topical application involves the absorption of a formulation by and/or
10 through skin, mucous membrane or wound tissue. Topical applications may
also be used to protect the skin or mucous membrane from external irritants
such as chemicals, biological fluids, sunlight, etc.

Conventional topical vehicles such as creams, lotions and ointments
often have attributes that reduce patient compliance and compromise efficacy.
15 For example ointments containing white petroleum as the carrier often form an
impermeable barrier, so that metabolic products and excreta from the area to
which they are applied are not easily removed or drained away. Furthermore, it
may be difficult for an active agent dissolved in the carrier to pass through the
white petrolatum barrier layer to the skin, so the efficacy of the drug is reduced.
20 In addition, ointments and creams often do not create an environment for
promoting normal respiration of the skin.

Foams for topical application are pressurized delivery forms containing
one or more ingredients that, upon valve actuation, emit a fine dispersion of
liquid and/or solid materials in a gaseous medium. Topical foams utilize
25 compressed gases of various types as propellants, including but not limited to
hydrocarbon gases (propane, butane, and isobutane), nitrogen, carbon dioxide,
freons, chlorofluorocarbons, and fluorocarbons.

Foam formulations are generally easier to apply, are less dense, and
spread more easily than other topical dosage forms. Foams may be formulated

in various ways to provide emollient or drying functions to the skin, depending on the formulation constituents.

Use of emulsions in foam compositions is known. Emulsion systems provide a two-phase system including lipophilic or hydrophobic components in one phase and hydrophilic components in the second phase. The foamed emulsion typically is an oil-in-water emulsion in which the hydrophobic component is dispersed in the aqueous continuous phase.

For example, WO 04/037225 to Foamix discloses an oil in water emulsion comprising 80-98% water; and US 20040106688 discloses an oil in water emulsion comprising from 50 to 97% by weight of a water phase.

US 20080044444 to Foamix discloses foamable compositions comprising a dicarboxylic acid or ester derivative thereof in which the dicarboxylic acid or ester derivative is a stabilizing emollient and or has a therapeutic effect.

US 20060281823 discloses a foamable water-in-oil type emulsion composition comprising diglyceride-containing fats and oils and a liquid sugar, having improved in-mouth meltability and thermostability with a low specific gravity and a good eating texture for use in buttercreams or similar products. The application does not disclose the use of such a composition comprising an active pharmaceutical ingredient. Foams and, in particular, foam emulsions are complicated systems which do not form under all circumstances. Slight shifts in foam emulsion composition, such as by the addition of active ingredients, may destabilize the foam.

SUMMARY OF THE INVENTION

The prior art does not disclose a foamable, water in oil emulsion for topical application

The present invention provides a foamable composition for topical application, the composition comprising a water in oil emulsion.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or
5 equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below.

Where ranges are given, endpoints are included within the range. Furthermore, it is to be understood that unless otherwise indicated or otherwise
10 evident from the context and understanding of one of ordinary skill in the art, values that are expressed as a range can assume any specific value or subrange within the stated range in different embodiments of the invention, to the tenth of the unit of the lower limit of the range, unless the context clearly dictates otherwise. Where a percentage is recited in reference to a value that intrinsically
15 has units that are whole numbers, any resulting fraction may be rounded to the nearest whole number.

In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

20

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides, in at least some embodiments, a foamable water in oil composition comprising an emulsion for topical application, providing a homogenous foam, which is surprisingly stable.

25 According to some embodiments, the present invention provides a foamable composition comprising a water in oil emulsion, the emulsion comprising up to about 40% (w/w) oil and up to about 60% (w/w) water.

According to some embodiments, the present invention provides a foamable composition comprising a water in oil emulsion, the emulsion

comprising up to about 40% (w/w) oil, up to about 60% (w/w) water and at least one surfactant.

According to some embodiments, the present invention provides a foamable composition for topical application, the composition comprising a water in oil emulsion comprising up to about 40% (w/w) oil, up to about 60% (w/w) water or hydrophilic liquid, and at least one surfactant providing an HLB value of less than about 7.

According to some embodiments, the present invention provides the use of a composition for topical application, wherein the composition comprises a water in oil emulsion adapted to be foamable.

According to some embodiments, the composition comprises an emulsion, the emulsion comprising at least one of zinc oxide, hyaluronic acid or zinc hyaluronate, optionally as an active ingredient, although the use of other active ingredients, including natural ingredients of plant or animal origin, such as, for example, Euphrasia Mallow, Chamomile, Hamamelis, or Aloe is considered as being within the scope of the invention. Zinc oxide is commonly used to treat minor burns and skin irritation, and is a preferred ingredient in many creams and ointments for the treatment or prevention of diaper rash.

The prior art does not teach a foamable composition comprising a water in oil emulsion, the emulsion comprising at least one of zinc oxide, hyaluronic acid, zinc hyaluronate or a plant extract.

According to some embodiments of the present invention, there is provided a foamable composition comprising an emulsion, the emulsion comprising up to about 25% (w/w of total composition) zinc oxide and up to about 40% (w/w of total composition) oil as a carrier in a water in oil emulsion.

According to some embodiments, there is provided a foamable composition comprising a water in oil emulsion, the emulsion comprising at least one of zinc oxide, hyaluronic acid, zinc hyaluronate, or a plant extract.

According to some embodiments, there is provided a foamable composition comprising a water in oil emulsion, the emulsion comprising at

least one of zinc oxide, hyaluronic acid, zinc hyaluronate, or a plant extract, and at least one surfactant.

According to some embodiments, there is provided a foamable water in oil composition comprising at least one of zinc oxide, hyaluronic acid, zinc hyaluronate, or a plant extract, and at least one surfactant comprising a fatty acid ester.

According to some embodiments, there is provided a foamable composition comprising a water in oil emulsion, the composition being adapted for delivery from a pressurized container, the emulsion comprising at least one of zinc oxide, hyaluronic acid, zinc hyaluronate, or a plant extract, wherein a foam is formed upon expulsion from said container.

According to some embodiments, there is provided a foamable composition comprising a water in oil emulsion for the treatment or prevention of a skin condition, the emulsion comprising at least one of zinc oxide, hyaluronic acid, zinc hyaluronate, or a plant extract.

According to some embodiments, there is provided a method for treating or preventing a skin condition, the method comprising administering to the skin a foamable water in oil composition comprising an emulsion, the emulsion comprising at least one of zinc oxide, hyaluronic acid, zinc hyaluronate, as an active ingredient.

According to some embodiments, the plant extract of the present invention may comprise one or more of Euphrasia Mallow, Chamomile, Hamamelis, and Aloe or similar.

According to some embodiments of the present invention, zinc oxide is preferably present at a concentration in the range of from about 2% to about 20% w/w of total composition.

The oil of the present invention may have a low polarity, such as, for example, one or more of mineral oil, triglyceride oil, squalane, tocopherol or its derivatives, avocado oil, macadamia oil, corn oil, olive oil, sesame oil, peanut oil, octyl dodecanate, or oleic acid decyl ester, or combinations thereof.

Alternatively or additionally, the oil may have a medium to high polarity. Non-limiting examples of suitable oils include isopropyl myristate, isopropyl palmitate, caprylic / capric triglycerides, propylene glycol dicaprylate / dicaprate, decyl oleate, dibutyl adipate, or hexyl laurate, or combinations thereof.

According to a preferred embodiment, the oil of the present invention comprises isopropyl myristate and mineral oil.

According to some embodiments of the present invention, the composition comprises at least one surfactant. Optionally and preferably, the surfactant or combination of surfactants has a total HLB of less than about 7.

Optionally and preferably, at least one surfactant comprises a fatty acid ester.

Examples of suitable fatty acid esters include but are not limited to sorbitan fatty acid esters (such as sorbitan monolaurate; sorbitan mono palmitate; sorbitan monooleate, sorbitan dioleate; sorbitan trioleate; sorbitan sesquioleate; sorbitan monolaurate; sorbitan monoisostearate; sorbitan diisostearate; sorbitan sesquisteate); sucrose fatty acid esters (such as sucrose monopalmitate; sucrose monostearate; sucrose distearate; sucrose polystearate); propylene glycol fatty acid esters (such as propylene glycol stearate; propylene glycol alginate); glyceryl fatty acid esters (such as glyceryl monooleate; glyceryl monostearate; glyceryl myristate); polyglyceryl fatty acid esters (such as polyglyceryl 2-stearate; polyglyceryl 2-oleate; polyglyceryl 2-dioleate; polyglyceryl 4-stearate; polyglyceryl 4-tristearate; polyglyceryl 6-laurate; polyglyceryl 6-stearate; polyglyceryl 6-tetrabehenate; polyglyceryl 10-laurate); polyethylene glycol fatty acid esters (such as PEG-2 stearate; PEG-4 stearate; PEG-10 stearate; PEG-25 stearate; PEG-2 oleate; PEG-8 distearate); polyoxyethylene stearates; or polyoxyethylene sorbitan fatty acid esters (such as polysorbate 20; polysorbate 40; polysorbate 60; polysorbate 80; polysorbate 85; PEG-20 sorbitan isostearate).

Optionally and preferably, the fatty acid ester surfactant comprises glyceryl monooleate. More preferably, the glyceryl monooleate is present at a concentration in the range of from about 0.2% to about 7% w/w of total composition.

5 Additionally or alternatively, the fatty acid ester surfactant comprises sucrose polystearate and sucrose distearate. Optionally and preferably, sucrose polystearate is present at a concentration of up to about 3% w/w of total composition, and sucrose distearate is present at a concentration of up to about 1% w/w of total composition. Optionally and more preferably, sucrose
10 polystearate is present at a concentration of about 0.3% w/w of total composition, and sucrose distearate is present at a concentration of about 0.1% w/w of total composition.

According to some embodiments of the present invention, the composition further comprises a co-emulsifier, such as, for example, beeswax,
15 lanolin, cetyl alcohol, stearyl alcohol, cetostearyl alcohol, stearic acid, palmitic acid or poloxamer. Optionally and preferably, the beeswax is present at a concentration of up to about 4% w/w of total composition. Optionally and more preferably, the beeswax is present at a composition of about 2% w/w of total composition. Also optionally and preferably, lanolin is present at a
20 concentration of up to about 7% w/w of total composition. Optionally and more preferably, the lanolin is present at a concentration of about 2% w/w of total composition.

According to some embodiments, the composition of the present invention further comprises panthenol. Panthenol is a humectant, emollient and
25 moisturizer, which improves hydration, reduces itching and inflammation of the skin and accelerates and improves healing of epidermal wounds. Optionally and preferably, panthenol is present at a concentration of up to about 5% w/w of total composition.

According to some embodiments, the composition of the present
30 invention further comprises aloe vera extract, which is considered to be

effective in the treatment of wounds. Optionally and preferably, the aloe vera extract is present at a concentration of up to about 1% w/w of total composition.

According to some embodiments, the composition of the present invention further comprises a preservative (such as, for example, benzalkonium chloride, sodium benzoate, benzoic acid, benzyl alcohol, methylparaben, ethylparaben, propylparaben, butylparaben, imidurea, potassium sorbate, sorbic acid, phenoxyethanol, chlorocresol, or bronopol).

According to some embodiments of the present invention, the composition further comprises a propellant, such as, for example, one or more hydrocarbon gases (propane, butane and isobutane) and/or fluorocarbons (such as Dymel 134a®).

The composition of the present invention is useful, in some embodiments, for the treatment or prevention of a skin condition, such as, for example, diaper rash, psoriasis, eczema, urticaria, scabies, acne, alopecia areata, bullous pemphigoid, dermatitis, atopic dermatitis, impetigo, keloids, pruritis, rosacea, vitiligo, burns, irritation, inflammation, fungal infection, dry skin, skin allergies or diabetic skin conditions.

The composition of the present invention is useful, in some embodiments, for providing a skin soothing and anti-itching effect.

The composition of the present invention is preferably useful, in some embodiments, for treatment or prevention of diaper rash.

Diaper rash is a generalized term indicating any skin irritation, regardless of cause, that develops in the diaper-covered region. While diaper rash is generally thought to affect infants and toddlers, any individual wearing a diaper (for example, an incontinent adult) is a candidate to develop this condition. Contact dermatitis is the most common category of diaper rash. Skin involvement may vary from mild redness to erosion of the top layers of skin. Other categories include skin infections and allergic reactions.

Oil in water foam compositions are problematic for treatment of diaper rash, since the composition is easily washed away by the urine and fecal excretions of the subject. Water in oil compositions are preferable in this respect; however, stable water in oil foaming compositions are very difficult to
5 formulate.

According to some embodiments, the composition of the present invention is a cosmetic composition for topical application. Such a composition may be useful for improving the appearance and/or texture of the skin.

10 According to some embodiments, the composition of the present invention may be provided as a medical device.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details set forth in the following description or exemplified by the Examples. The
15 invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

As used herein the term "about" refers to $\pm 10\%$.

20 Pharmaceutical compositions suitable for use in the context of the present invention include compositions wherein the active ingredient is contained in an amount effective to achieve the intended purpose. More specifically, a "therapeutically effective amount" means an amount of active ingredient effective to prevent, alleviate, or ameliorate a skin condition.

25 Determination of a therapeutically effective amount is well within the capability of those skilled in the art, especially in light of the detailed disclosure provided herein.

Additional objects, advantages, and novel features of the present invention will become apparent to one ordinarily skilled in the art upon
30 examination of the following examples, which are not intended to be limiting.

Additionally, each of the various embodiments and aspects of the present invention as delineated hereinabove and as claimed in the claims section below finds experimental support in the following examples.

5

EXAMPLES

Example 1

Material	Amount (g)
Light mineral oil	280
Isopropyl myristate	140
Lanolin	70
White beeswax	56
Simulsol 165™	2.8
Glyceryl monooleate	18.2
Sucrose polystearate	28
Arlatone 2121®	2.8
Arlacel 135®	5.6
Brij 52®	42
Zinc oxide	140
Xanthan gum	5.6
Dexpanthenol	28
Propylene glycol	28
Benzalkonium chloride 50%	2.9
Aloe vera dry extract	1.4
Magnesium sulphate	2.8
Purified water	536.2
Perfume essence 337HBV	2.8

The general method of production for this example was as follows:

The emulsion was prepared by heating the components of the oil phase and those of the aqueous phase separately to a temperature of between 60°C and 80°C. The phases were then mixed, homogenized and cooled to room temperature. Conductivity of the emulsion was measured according to the manufacturer's instructions, using the OysterTM conductivity/temperature meter (Extech Instruments Corporation, Waltham, MA, USA). The low conductivity obtained showed the emulsion to be of the water in oil type.

Foamability of the emulsion was demonstrated by packing in an aluminium can fitted with a delivery valve and pressurizing with a suitable propellant comprising one or more hydrocarbon gases such as propane, butane and isobutane.

Similar procedures were employed for the examples that follow.

Example 2

Material	Amount (g)
Light mineral oil	383.6
Isopropyl myristate	140
Lanolin	70
White beeswax	42
Simulsol 165 TM	4.9
Glyceryl monooleate	14
Sucrose polystearate	28
Brij 52®	21
Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Propylene glycol	28

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Benzalkonium chloride 50%	2.8
Aloe vera dry extract	1.4
Magnesium sulphate	2.8
Purified water	490

Example 3

Material	Amount (g)
Light mineral oil	383.6
Isopropyl myristate	140
Lanolin	70
White beeswax	42
Simulsol 165™	4.9
Glyceryl monooleate	28
Sucrose polystearate	14
Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Propylene glycol	28
Benzalkonium chloride 50%	2.8
Aloe vera dry extract	1.4
Magnesium sulphate	2.8
Purified water	511

Example 4

Material	Amount (g)
Light mineral oil	373.8
Isopropyl myristate	140
Lanolin	70
White beeswax	28
Simulsol 165™	4.9
Glyceryl monooleate	28
Sucrose polystearate	16.8
Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Propylene glycol	28
Benzalkonium chloride 50%	2.8
Aloe vera dry extract	1.4
Magnesium sulphate	2.8
Purified water	532

Example 5

Material	Amount (g)
Light mineral oil	373.8
Isopropyl myristate	84
Lanolin	70
White beeswax	28
Simulsol 165™	4.9

Glyceryl monooleate	28
Sucrose polystearate	16.8
Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Propylene glycol	28
Benzalkonium chloride 50%	2.9
Aloe vera dry extract	1.4
Magnesium sulphate	2.8
Purified water	588

Example 6

Material	Amount (g)
Light mineral oil	336
Isopropyl myristate	84
Lanolin	56
Beeswax substitute	28
Simulsol 165™	2.1
Glyceryl monooleate	16.8
Sucrose polystearate	21
Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Propylene glycol	28
Benzalkonium chloride 50%	2.8

15

Aloe vera dry extract	1.4
Magnesium sulphate	2.8
Purified water	649.6

Example 7

Material	Amount (g)
Light mineral oil	371.7
Isopropyl myristate	84
Lanolin	70
Beeswax substitute	28
Sucrose distearate	4.2
Glyceryl monooleate	16.8
Sucrose polystearate	21
Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Propylene glycol	28
Methylparaben	2.52
Propylparaben sodium	0.28
Aloe vera dry extract	1.4
Magnesium sulphate	2.8
Purified water	597.8

Example 8

Material	Amount (g)
Light mineral oil	361.9
Isopropyl myristate	84
Lanolin	70
Beeswax substitute	28
Sucrose distearate	4.2
Glyceryl monooleate	16.8
Sucrose polystearate	21
Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Propylene glycol	28
Phenoxyethanol	10.14
Potassium sorbate	2.8
Aloe vera dry extract	1.4
Magnesium sulphate	2.8
Purified water	597.8

Example 9

Material	Amount (g)
Light mineral oil	373.8
Isopropyl myristate	84
Lanolin	70
White beeswax	28
Arlacel 165®	2.1

Glyceryl monooleate	16.8
Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Benzalkonium chloride 50%	2.8
Aloe vera dry extract	1.4
Magnesium sulphate	2.8
Purified water	625.8

Example 10

Material	Amount (g)
Light mineral oil	371.7
Isopropyl myristate	84
Lanolin	70
White beeswax	28
Sucrose distearate	4.2
Glyceryl monooleate	16.8
Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Benzalkonium chloride 50%	2.8
Aloe vera dry extract	1.4
Magnesium sulphate	2.8
Purified water	625.8

Example 11

Material	Amount (g)
Light mineral oil	371.7
Isopropyl myristate	84
Lanolin	70
White beeswax	28
Sucrose distearate	4.2
Glyceryl monooleate	16.8
Sucrose polystearate	21
Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Benzalkonium chloride 50%	2.8
Aloe vera dry extract	1.4
Purified water	625.8

Example 12

Material	Amount (g)
Light mineral oil	373.8
Isopropyl myristate	84
Lanolin	70
White beeswax	28
Arlacel 165®	2.1
Glyceryl monooleate	16.8
Sucrose polystearate	21
Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Methylparaben sodium	2.52
Propylparaben sodium	0.28
Aloe vera dry extract	1.4
Purified water	625.8

Example 13

Material	Amount (g)
Light mineral oil	377.3
Isopropyl myristate	84
Lanolin	70
White beeswax	28
Sucrose distearate	4.2
Glyceryl monooleate	28
Sucrose polystearate	4.2

20

Zinc oxide	140
Xanthan gum	3.5
Dexpanthenol	28
Methylparaben sodium	2.52
Propylparaben sodium	0.28
Aloe vera dry extract	1.4
Purified water	628.6

Example 14

Material	Amount (g)
Light mineral oil	322
Isopropyl myristate	84
Lanolin	28
White beeswax	42
Sucrose distearate	4.2
Glyceryl monooleate	28
Sucrose polystearate	14
Zinc oxide	140
Dexpanthenol	28
Methylparaben sodium	2.52
Propylparaben sodium	0.28
Aloe vera dry extract	1.4
Purified water	705.6

Example 15

Material	Amount (g)
Light mineral oil	294
Isopropyl myristate	70
Lanolin	70
White beeswax	28
Sucrose distearate	4.2
Glyceryl monooleate	16.8
Sucrose polystearate	14
Zinc oxide	140
Dexpanthenol	28
Methylparaben sodium	2.52
Propylparaben sodium	0.28
Aloe vera dry extract	1.4
Purified water	730.8

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

WHAT IS CLAIMED IS:

1. A foamable composition comprising a water in oil emulsion, said emulsion comprising up to about 40% (w/w) oil, up to about 60% (w/w) water and at least one surfactant.
2. A foamable composition for topical application, the composition comprising a water in oil emulsion, said emulsion comprising up to about 40% (w/w) oil, up to about 60% (w/w) water or hydrophilic liquid, and at least one surfactant providing an HLB value of less than about 7.
3. Use of a composition comprising a water in oil emulsion for topical application, said composition adapted to be foamable.
4. A foamable composition comprising a water in oil emulsion, the emulsion comprising at least one of zinc oxide, hyaluronic acid, zinc hyaluronate, or a plant extract.
5. The foamable composition of claim 4, wherein said at least one of zinc oxide, hyaluronic acid, zinc hyaluronate, or a plant extract as an active ingredient.
6. A foamable composition comprising a water in oil emulsion, the emulsion comprising at least one of zinc oxide, hyaluronic acid, zinc hyaluronate, or a plant extract and at least one surfactant.

7. A foamable composition comprising a water in oil emulsion, the emulsion comprising zinc oxide hyaluronic acid, zinc hyaluronate, or a plant extract and a surfactant comprising a fatty acid ester.

8. A foamable composition comprising a water in oil emulsion for the treatment or prevention of a skin condition, the emulsion comprising at least one of zinc oxide, hyaluronic acid, zinc hyaluronate, or a plant extract.

9. A method for treating or preventing a skin condition, the method comprising applying to the skin a foamable water in oil composition comprising at least one of zinc oxide, hyaluronic acid, zinc hyaluronate, or a plant extract.

10. The composition of any of claims 1, 2, 3, 4, 6, or 7 for cosmetic application.

11. A foamable composition comprising a water in oil emulsion adapted for delivery from a pressurized container, the emulsion comprising at least one of zinc oxide, hyaluronic acid, zinc hyaluronate, or a plant extract wherein a foam is formed upon expulsion from said container.

12. The composition or method of any of claims 4 to 9 or 11, wherein said plant extract comprises at least one of Euphrasia Mallow, Chamomile, Hamamelis, and Aloe.

13. A foamable composition comprising up to about 25% (w/w of total composition) zinc oxide and up to about 40% (w/w of total composition) oil in a water in oil emulsion.

14. The composition, use or method of any of claims 1 to 13, wherein said oil comprises one or more of a low polarity oil, or a medium to high polarity oil, or combinations thereof.

15. The composition, use or method of claim 14, wherein said low polarity oil comprises one or more of mineral oil, triglyceride oil, squalane, tocopherol or its derivatives, avocado oil, macadamia oil, corn oil, olive oil, sesame oil, or peanut oil, or combinations thereof.

16. The composition, use or method of claim 14, wherein said medium to high polarity oil comprises one or more of isopropyl myristate, isopropyl palmitate, caprylic / capric triglycerides, propylene glycol dicaprylate / dicaprinate, decyl oleate, dibutyl adipate, or hexyl laurate, or combinations thereof.

17. The composition, use or method of claim 14, wherein said oil comprises isopropyl myristate and mineral oil.

18. The use or method of any of claims 3, or 9, wherein said composition further comprises at least one surfactant.

19. The composition of any of claims 4, 5, 8, or 10 to 13, wherein said composition further comprises at least one surfactant.

20. The composition, use or method of any of claims 2, 3, 6, or 19, wherein said surfactant comprises a fatty acid ester.

21. The composition, use or method of any of claims 7 or 20, wherein said fatty acid ester comprises one or more of sorbitan monolaurate; sorbitan mono palmitate; sorbitan monooleate, sorbitan dioleate; sorbitan

trioleale; sorbitan sesquioleate; sorbitan monolaurate; sorbitan monoisostearate; sorbitan diisostearate; sorbitan sesquisteate; sucrose monopalmitate; sucrose monostearate; sucrose distearate; sucrose polystearate; propylene glycol stearate; propylene glycol alginate; glyceryl monooleate; glyceryl monostearate; glyceryl myristate; polyglyceryl 2-stearate; polyglyceryl 2-oleate; polyglyceryl 2-dioleate; polyglyceryl 4-stearate; polyglyceryl 4-tristearate; polyglyceryl 6-laurate; polyglyceryl 6-stearate; polyglyceryl 6-tetrabehenate; polyglyceryl 10-laurate PEG-2 stearate; PEG-4 stearate; PEG-10 stearate; PEG-25 stearate; PEG-2 oleate; PEG-8 distearate; polyoxyethylene stearates; polysorbate 20; polysorbate 40; polysorbate 60; polysorbate 80; polysorbate 85; and PEG-20 sorbitan isostearate, or combinations thereof.

22. The composition, use, or method of claim 21, wherein said fatty acid ester comprises glyceryl monooleate at a concentration in the range of from about 0.2% to about 7% w/w of total composition.

23. The composition, use or method of any of claims 2, 3, 6, 7, or 19 to 22, wherein said surfactant comprises sucrose polystearate and sucrose distearate.

24. The composition, use or method of claim 23, wherein said sucrose polystearate is present at a concentration of up to about 6% w/w of total composition, and said sucrose distearate is present at a concentration of up to about 4% w/w of total composition.

25. The composition, use or method of any of claims 2, 3, 6, 7, or 19 to 24, further comprising a co-emulsifier.

26. The composition, use or method of claim 25, wherein said co-emulsifier comprises one or more of beeswax, lanolin, cetyl alcohol, stearyl alcohol, cetostearyl alcohol, stearic acid, palmitic acid and poloxamer.

27. The composition, use or method of claim 26, wherein said beeswax is present at a concentration of up to about 6% w/w of total composition.

28. The composition, use or method of claim 26, wherein said lanolin is present at a concentration of up to about 7% w/w of total composition.

29. The composition, use or method of any of claims 1 to 28, further comprising panthenol.

30. The composition, use or method of claim 29, wherein said panthenol is present at a concentration of up to about 5% w/w of total composition.

31. The composition, use or method of any of claims 1 to 30, further comprising aloe vera extract.

32. The composition, use or method of any of claims 1 to 31 for the treatment or prevention of a skin condition.

33. The composition, use, or method of claim 32, wherein said skin condition comprises one or more of diaper rash, psoriasis, eczema, urticaria, scabies, acne, alopecia areata, bullous pemphigoid, dermatitis, atopic dermatitis, impetigo, keloids, pruritis, rosacea, vitiligo, burns, irritation, inflammation, fungal infection, dry skin, skin allergies or diabetic skin conditions.

34. The composition, use, or method of any of claims 1 to 33, for providing a skin soothing and/or anti-itching effect.

35. The composition, use or method of any claims 1 to 34, further comprising one or more propellant gases.

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2010/000096

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K8/04 A61K8/92 A61K9/12 A61Q19/00 A61K9/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61K A61Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, CHEM ABS Data, EMBASE, MEDLINE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2007/007208 A2 (FOAMIX LTD [IL]; TAMARKIN DOV [IL]; EINI MEIR [IL]; FRIEDMAN DORON [IL]) 18 January 2007 (2007-01-18)	1-11, 13-21, 25, 29, 32-35
Y	example 7 [0089]	12, 22-24, 26-28, 30, 31
X	WO 2004/037225 A2 (FOAMIX LTD [IL]; TAMARKIN DOV [IL]; FRIEDMAN DORON [IL]; EINI MEIR [IL]) 6 May 2004 (2004-05-06) example 18 ----- -/--	1-11, 13-21, 25, 29, 32-35

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"&" document member of the same patent family

Date of the actual completion of the international search

30 April 2010

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07/05/2010

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INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	WO 2007/085902 A2 (FOAMIX LTD [IL]; TAMARKIN DOV [IL]; FRIEDMAN DORON [IL]; EINI MEIR [IL]) 2 August 2007 (2007-08-02) [0089] -----	12,31

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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WO 2007085902 A2	02-08-2007	NONE	