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(54) Title: MEDICATED SKIN CLEANSING PRODUCTS COMPRISING AN ANTIMYCOTIC AGENT

(57) Abstract: The invention provides a medicated skin cleansing product for treatment or prevention of skin disorders comprising a synthetic surfactant and an antimycotic, having a pH of between 5.0-8.0.

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MEDICATED SKIN CLEANISING PRODUCTS COMPRISING AN ANTIMYCOTIC AGENT

The present invention relates to a medicated skin cleansing product. More particularly, the present invention relates to skin cleansing products for treatment or prevention of skin disorders comprising a synthetic surfactant and an antimycotic agent, which products can be soap free, i.e. a synthetic surfactant soap or a combination of soap and a synthetic surfactant, referred to as a Combo product. The skin cleansing products of the present invention are especially formulated for treatment or prevention of skin disorders and are characterized by having a pH of 5.0 to 8.0.

In British Patent 2342862 there is described and claimed a solid cleansing soap bar containing an anti-fungal agent for treatment of mycotic skin disorders wherein said chemical composition is defined as having a pH between 6-10 and being formed into a solid bar cake that is usable as a cleansing bar. The said soaps were in fact alkaline metal soaps, known to exhibit a very high pH value (8-10), (being salts of weak acids with strong bases) so the lower pH range (5.0-8.0) could not have been substantiated.

Unlike alkaline soaps, the synthetic detergents (otherwise known as soap-free soaps or syndet) can be formulated at lower pH values, compatible with the normal skin pH range.

As the pH of the skin is mostly acidic (4.5-5.5) up to neutral (5.5-7.0) it has been an object of the present invention to develop medicated products containing antimycotics and having a pH encompassing the normal skin range.

In addition, a pH of say between 5.0 to 8.0, that does not disturb the physiological equilibrium of the natural bacterial flora, is desirable since a product with a pH of between 8 to 10 will disturb the natural physiological pH, raising the skin pH for a certain period of time, from minutes to hours, depending on the pH of the product (the higher the worse). During this time the overgrowth of the fungi will be accelerated.

As will be described hereinafter it has now been found that the products of the present invention do not change the skin's natural pH, leaving intact the competitive inhibition between the natural bacterial flora and fungi.

Thus, according to the present invention there are now provided a medicated skin cleansing product for treatment or prevention of skin disorders comprising a synthetic surfactant and an antimycotic and having a pH of between 5.0-8.0.

It is to be noted that the chemical composition claimed in claim 2 of BP 2342682 is: "A composition in which the base compound has low foaming qualities when dissolved in water".

Poor foaming performance is considered to be a serious drawback of a cleansing bar product leading to a serious consumer dissatisfaction.

Due to the use of synthetic surfactants the products of the present invention posses high foaming properties when dissolved in water and high foaming performance under practical usage. The products of the present invention posses novel properties in comparison with prior art products since the present invention provides for the first time a medicated soap with antimycotics containing a combination of soap and synthetic surfactants, exhibiting advantageous properties.

In preferred embodiments of the present invention said products contain only ingredients of vegetable origin the soap being based on renewable vegetable sources such as palm, palm-kernel and coconut.

The same vegetable sources are preferably used for the surfactant ingredients.

The chemical composition claimed in claim 1 of BP 2342682 is "formed into a solid bar cake that is usable as a cleansing bar".

The meaning of this claim, further supported by the formulation example described in the patent, is that the soap is made by a molding process which comprises a melting stage of all the ingredients ,followed by a casting stage ,in which the molten liquid composition is poured and "formed into a solid bar cake". The molding process implies, by its nature, some formulation limitations, leading to some disadvantages under practical usage of the soap, such as increased mushiness and high water solubility. According to the example described, the soap is of a translucent appearance, characterized by the above quoted drawbacks under practical usage.

Moreover, the process is of low production efficiency, being currently performed on a batch scale, at a high production cost.

In contradistinction the products of the present invention are preferably made by an extrusion process, providing a novel process to the present state of art, for the continuous production of soap free and combo bars which assure substantial improvement in unit costs, enhances the volume of production and better flexibility in product formulation and production conditions (such as lower in-process temperatures). Moreover the bars of the present invention have favourable under usage properties, such as normal mushiness and moderate water solubility, well appreciated by the consumer.

The medicated soap or soap-free products of the present invention can be used for the treatment or prevention of skin disorders wherein the skin disorder is selected form the group consisting of mycotic, fungal, itching, rash, dermatitis, tinea crusis, body tinea, eczema, pruritus and dermatophytosis.

Preferably the antimycotic used in the product of the present invention is selected from the group consisting of terbinafine or ciclopirox and imidazoles.

More specifically the antimycotic agent is preferrably selected from the group consisting of Clotrimazole, Miconazole, Metronidazole, Bifonazole, Ketoconazole, Terconazole, Econazole Terbinafine, Ciclopirox or mixtures thereof.

In especially preferred embodiments of the present invention said antimycotic is Clotrimazole or Miconazole..

Said antimycotic is preferably provided in a concentration of between 0.5 and 2.0%.

The composition of the basic soap-free cleansing bar is based on a clinically proven, dermatologically tested product containing allergy-screened ingredients.

The cleansing bars according to the present invention have been shown to have better substantivity properties, so that the quantity of the antimycotic left on the skin is relatively high.

As stated hereinbefore in the preferred embodiments of the present invention the medicated skin cleansing product is soap-free or is primarily soap-free, e.g., is in the form of a combination bar having up to 20% of a soap product and having at least 80% of a soap-free product containing the antimycotic component.

In especially preferred embodiments of the present invention said product is in the form of a cleansing bar while in other embodiments said product is in the form of a liquid soap-free soap.

The novel anti-mycotic solid preparations are advantageously prepared by heating the various ingredients together at an elevated temperature as to obtain an intimate fluid or semi-fluid mixture, cooling down the mixture to a lower temperature so as to remain still in a semi-fluid extrudable state, adding thereto the antimycotic, and extruding, casting or shaping by other means a desired shape, such as bar, stick or the like.

Some of the preparations were initially heated to about 70-85°C, cooled to about 50-65°C, the antimycotic was added and the desired shape of the final product (of the desired shape) was prepared.

The pH of the preparation may advantageously be adjusted to a pH in the said range. The pH can be adjusted by the addition of suitable physiologically acceptable acids. Various acids are suited for this purpose, such as lactic, citric and phosphoric acid.

In a first set of preferred embodiments of the present invention there is provided a skin cleansing bar composition containing formulations ingredients, such as for example:

a) 20-70% of anionic surfactants chosen from a large variety of mild surfactants such as: disodium alkyl sulfosuccinates (C_{10}-C_{18}), sodium/potassium long chain alkyl sulfate (C_{10}-C_{20}), sodium cocoyl isethionate, sodium alkyl sulfoacetate, acyl taurates, acyl sarcosinates, acyl glutamate, alkyl glyceryl ether sulfonates, and mixtures thereof;

b) 0-10% of amphoteric and cationic surfactants, such as alkylamido propyl betaine, alkyl betaine, alkyl sultaines, alkyl amine oxides and imidazolines and mixtures thereof;

c) 0-10% of nonionic surfactants such as alkyl polyglucosides, polyalkylene glycols, glyceryl monostearate, polyetoxylated fatty alcohols, polyhydroxy fatty acid amides and alkanolamides and mixtures thereof;

d) 2-20% of binders and plasticizers, such as cetostearyl alcohol, paraffin wax, stearic acid, palmitic acid, myristic acid, polyol esters, polyethylene glycols, fatty acid ethoxylate and mixtures thereof, whesaid plasticizers have a melting point from about 30 to 90 ° C;

e) 5-30% of moisturizing agents and emollients, such as: stearic acid, cetostearyl alcohol, mineral oil, vegetable oil, urea, glycerine, propylene glycol, lactic acid, sodium lactate, polyols and mixtures thereof;

f) 10-30% of binding agents and processing aid agents such as maltodextrin, dextrin, starch, talc and mixtures thereof;

g) 0.2%-5% of antimycotic agent, preferably Clotrimazole or Miconazole;

h) 0.5%-5% of skin substantivity increasing agents such as quaternized polymers, sodium acrylates copolymer and cationic copolymers and mixtures thereof; and

i) 0.2-5% of pH adjusting acid agents such as lactic acid, phosphoric acid, citric acid, fumaric acid, tartaric acid and mixtures thereof.

In further embodiments of the present invention there is provided an antifungal soap-free cleansing bar, comprising:

20-70% anionic surfactants, preferably 30-50%

0-10% amphoteric surfactants, preferably 2-4%

0-10% nonionic surfactants, preferably 1-4%.

10-50% moisturizers, emollients, plasticizers, preferably 15-35%

10-30% binding and processing aid agents, preferably 15-25%

0.2-5% antimycotic, preferably 0.5-2%

3-10% water, preferably 5-8%.

Preferably said compositions further comprise deionized water in an amount of between 3% and 10% (m/m).

In further embodiments of the present invention there is provided a combination skin cleansing bar composition comprising:

20-50% of anionic surfactants chosen from a large variety of mild surfactants such as: disodium alkyl sulfosuccinates (C_{10}-C_{18}), sodium/potassium long chain alkyl sulfate (C_{10}-C_{20}), sodium cocoyl isethionate, sodium alkyl sulfoacetates, acyl taurates, acyl sarcosinates, acyl glutamat, alkyl glyceryl ether sulfonates, and mixtures thereof;

0-20% of amphoteric and cationic surfactants, such as alkylamido propyl betaine, alkyl betaine, imidazolines and mixtures thereof;

0-10% of nonionic surfactants such as glyceryl monostearate, polyalkylene glycols, polyetoxylated fatty alcohos, polyhydroxy fatty acid amides, alkyl polyglucosides, alkanolamides and mixtures thereof;

0-20% of soap, of animal or vegetable origin such as, sodium tallowate, sodium palmate, sodium cocoate, sodium stearate, sodium palm kernelate, as a processing aid agent and hardener;

2-20% of binders and plasticizers, such as cetostearyl alcohol, paraffin wax, stearic acid, palmitic acid, myristic acid, wherein said plasticizers have a melting point from about 30 to 90°C.;

5-30% of moisturizing agents and emollients, such as: stearic acid, cetostearyl alcohol, mineral oil, vegetable oil, urea, glycerine, propylene glycol, lactic acid, sodium lactate, polyols and mixtures thereof;

10-30% of binding agents and processing aid agents such as maltodextrin, dextrin, starch, talc and mixtures thereof;

0.2%-5% of antimycotic agent, preferably Clotrimazole or Miconazole;

0.5%-5% of skin substantivity increasing agents such as quaternized polymers, sodium acrylate copolymers, cationic copolymers and mixtures thereof; and

0.2-5% of pH adjusting acid agents such as lactic acid, phosphoric acid, citric acid, fumaric acid, tartaric acid and mixtures thereof.

In further preferred embodiments of the present invention there is provided an anti-fungal combination cleansing bar comprising:

20-50% anionic surfactants, preferably 30-45%;

0-20% soap preferably 6-10%;

0-10% nonionic surfactants preferably 1-4%;

0-10% amphoteric surfactants, preferably 2-4%;

10-50% moisturizers, emollients, plasticizers, preferably 15-35%;

10-30% binding and processing aid agents, preferably 15-25%;

0.2-5% Clotrimazole, Miconazole (or other antimycotic agent) preferably 0.5-2%; and

5-13% water, preferably 6-10%.

Preferably said compositions further comprise deionized water in an amount of between 5% and 13% (m/m).

While the invention will now be described in connection with certain preferred embodiments in the following examples so that aspects thereof may be more fully understood and appreciated, it is not intended to limit the invention to these particular embodiments. On the contrary, it is intended to cover all alternatives, modifications and equivalents as may be included within the scope of the invention as defined by the appended claims. Thus, the following examples which include preferred embodiments will serve to illustrate the practice of this invention, it being understood that the particulars shown are by way of example and for purposes of illustrative discussion of preferred embodiments of the present invention only and are presented in the cause of providing what is believed to be the most useful and readily understood description of product procedures as well as of the principles and conceptual aspects of the invention.

Examples 1-3: Soap-Free Bars

INGREDIENTS	% (*)		
	1	2	3
Sodium/Potassium Alkyl Sulfate	10	22	-
Disodium Lauryl Sulfosuccinate	10	23	15
Sodium Cocoyl Isethionate	20	-	30
Alkyl Polyglucoside	-	2	-
Stearic Acid	-	2	25
Palmitic Acid	-	2	-
Cetostearyl Alcohol	21	15	-
Alkylamido Propyl Betaine	2	-	-
Parafin Wax	4	3	-
Glycerine	1	2	2
Propylene Glycol	-	1	-
Dextrin	7.5	3	6
Starch	13	10	8
Talc	-	3.5	-
Lactic Acid	1	-	-
Citric Acid	0.5	0.5	2
Phosphoric Acid	-	0.5	-
Clotrimazole	1	1	1
Sodium Chloride	1	0.5	-
Water	7	8	10
Fragrance	1	1	1

(x) ALL THE PERCENTAGES CALCULATED ON 100% PURE INGREDIENTS

Examples 4-5: Combo Bars

INGREDIENTS	% (*)	
	4	5
Sodium/Potassium Alkyl Sulfate	5	-
Disodium Lauryl Sulfosuccinate	10	13
Sodium Cocoyl Isethionate	25	30
Soap	10	2.5
Stearic Acid	20	20
Palmitic Acid	5	2
Cetostearyl Alcohol	-	3
Alkylamido Propyl Betaine	-	1
Parafin Wax	-	-
Glycerine	1	1
Propylene Glycol	1	1
Dextrin	5	3
Starch	4	6
Talc	-	-
Clotrimazole	1	1
Water	10	11
Fragrance	1	1
Citric Acid	2	2

(x) ALL THE PERCENTAGES CALCULATED ON 100% PURE INGREDIENTS

It will be evident to those skilled in the art that the invention is not limited to the details of the foregoing illustrative examples and that the present invention may be embodied in other specific forms without departing from the essential attributes thereof, and it is therefore desired that the present embodiments and examples be considered in all respects as illustrative and not restrictive, reference being made to the appended claims, rather than to the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

WHAT IS CLAIMED IS:

1. A medicated skin cleansing product for treatment or prevention of skin disorders comprising a synthetic surfactant and an antimycotic, having a pH of between 5.0-8.0.
2. A medicated skin cleansing product according to claim 1 further comprising up to 20% soap.
3. A product according to claim 1 wherein the product is in the form of a cleansing bar.
4. A product according to claim 1 wherein the product is in the form of a liquid soap.
5. A product according to claim 1 which possesses good foaming qualities when dissolved in water and good foaming performance under practical usage.
6. A product according to claim 1 wherein said antimycotic is selected from the group consisting of Clotrimazole, Miconazole, Metronidazole, Bifonazole, Ketoconazole, Terconazole, Econazole Terbinafine, Ciclopirox or mixtures thereof.
7. A product according to claim 1, wherein the concentration of said antimycotic is between 0.1-5%.
8. A skin cleansing composition for the treatment or prevention of skin disorders according to claim 1 wherein said antimycotic is selected from the group consisting of Clotrimazole and Miconazole, and the concentration thereof is between 0.5-2.0%.
9. A medicated product according to claim 1 for the treatment or prevention of skin disorders containing an antimycotic and having a pH between 5.0-8.0 and further comprising up to 20% soap, wherein the skin disorder is selected form the group consisting of mycotic, fungal, itching, rash, dermatitis, tinea crusis, body tinea, eczema, pruritus and dermatophytosis.
10. A skin cleansing bar product according to claim 1 comprising:

    20-70% of anionic surfactants;

    0-10% of amphoteric and cationic surfactants;

    0-10% of nonionic surfactants;

    2-20% of binders and plasticizers, wherein said plasticizers have a melting point from about 30 to 90 ° C;

    5-30% of moisturizing agents and emollients;

10-30% of bind and processing aid agents;

0.2%-5% of antimycotic agent;

0.5%-5% of skin substantivity increasing agents; and

0.2-5% of pH adjusting acid agents.

11. A skin cleansing bar product according to claim 10 wherein said anionic surfactants are selected from the group consisting of disodium alkyl sulfosuccinates (C_{10}-C_{18}), sodium/potassium long chain alkyl sulfate (C_{10}-C_{20}), sodium cocoyl isethionate, sodium alkyl sulfoacetate, acyl taurates, acyl sarcosinates, acyl glutamate, alkyl glyceryl ether sulfonates, and mixtures thereof.

12. A skin cleansing bar product according to claim 10 wherein said amphoteric and cationic surfactants are selected from the group consisting of alkylamido propyl betaine, alkyl betaine, alkyl sultaines, alkyl amine oxides and imidazolines and mixtures thereof.

13. A skin cleansing bar product according to claim 10 wherein said non-ionic surfactants are selected from the group consisting of alkyl polyglucosides, polyalkylene glycols, glyceryl monostearate, polyetoxylated fatty alcohols, polyhydroxy fatty acid amides and alkanolamides and mixtures thereof.

14. A skin cleansing bar product according to claim 10 wherein said binders and plasticizers are selected from the group consisting of cetostearyl alcohol, paraffin wax, stearic acid, palmitic acid, myristic acid, polyol esters, polyethylene glycols, fatty acid ethoxylate and mixtures thereof.

15. A skin cleansing bar product according to claim 10 wherein moisturizing agents and emollients are selected from the group consisting of stearic acid, cetostearyl alcohol, mineral oil, vegetable oil, urea, glycerine, propylene glycol, lactic acid, sodium lactate, and polyols and mixtures thereof.

16. A skin cleansing bar product according to claim 10 wherein said binding and processing aid agents are selected from the group consisting of maltodextrin, dextrin, starch and talc and mixtures thereof.

17. A skin cleansing bar product according to claim 10 wherein said pH adjusting agents are selected from the group consisting of lactic acid, phosphoric acid, citric acid, fumaric acid and tartaric acid and mixtures thereof.

18. A skin cleansing bar product according to claim 10 wherein said skin substantivity increasing agents are selected from the group consisting of quaternized polymers, sodium acrylate copolymers and cationic copolymers and mixtures thereof.

19. A skin cleansing bar product according to claim 10 wherein said antimycotic agent is selected from the group consisting of Clotrimazole and Miconazole.

20. An antifungal soap-free cleansing bar according to claim 1, comprising:
20-70% anionic surfactants;
0-10% amphoteric surfactants;
0-10% nonionic surfactants;
10-50% moisturizers, emollients, plasticizers;
10-30% binding and processing aid agents;
0.2-5% Clotrimazole or Miconazole; and
3-10% water.

21. An antifungal soap-free cleansing bar according to claim 20 comprising:
30-50% anionic surfactants;
2-4% amphoteric surfactants;
1-4% nonionic surfactants;
15-35% moisturizers, emollients, plasticizers;
15-25% binding and processing aid agents;
0.5-2% Clotrimazole or Miconazole; and
5-8% water.

22. A skin cleansing composition according to claim 1 which further comprises stearic acid in an amount effective to serve as a moisturizing agent and/or emollient.

23. A skin cleansing composition according to claim 22, in which the stearic acid is present in a concentration of between 5 and 30%.

24. A skin cleansing composition as claimed in any one of the preceding claims, which further comprises glycerin in an amount effective to serve as a lubricating and moisturizing agent.

25. A skin cleansing composition according to claim 24, in which the glycerin is present in a concentration of between 0.5 and 5%.

26. A skin cleansing composition according to claim 24, in which the glycerin is present in an amount of 2%.

27. A skin cleansing composition according to claim 1, which further comprises propylene glycol in an amount effective to serve as a solvent for the components forming part of the composition.

28. A skin cleansing composition according to claim 27, in which the propylene glycol is present in a concentration of between 0.5% and 5%.

29. A skin cleansing composition according to claim 27, in which the propylene glycol is present in an amount of 1%.

30. A skin cleansing composition according to claim 1, which further comprises deionised water in an amount of between 3% and 10% (m/m).

31. A skin cleansing combination bar composition according to claim 1 comprising:

i) 20-50% of anionic surfactants;

ii) 0-10% of amphoteric and cationic surfactants;

iii) 0-10% of nonionic surfactants;

iv) 0.1-20% of soap, of animal or vegetable origin;

v) 2-20% of binders and plasticizers;

vi) 5-30% of moisturizing agents and emollients;

vii) 10-30% of binding agents and processing aid agents;

viii) 0.2%-5% of antimycotic agent;

ix) 0.5%-5% of skin substantivity increasing agents; and

x) 0.2-5% of pH adjusting acid agents

32. A skin cleansing combination bar product according to claim 31 wherein said anionic surfactants are selected from the group consisting of disodium alkyl sulfosuccinates (C_{10}-C_{18}), sodium/potassium long chain alkyl sulfate (C_{10}-C_{20}), sodium cocoyl isethionate, sodium alkyl sulfoacetates, acyl taurates, acyl sarcosinates, acyl glutamates, alkyl glyceryl ether sulfonates, and mixtures thereof.

33. A skin cleansing bar product according to claim 31 wherein said amphoteric and cationic surfactants are selected from the group consisting of alkylamido propyl betaine, alkyl betaine, imidazolines and mixtures thereof.

34. A skin cleansing bar product according to claim 31 wherein said nonionic surfactants are selected from the group consisting of glyceryl monostearate, polyalkylene glycols, polyetoxylated fatty alcohos, polyhydroxy fatty acid amides, alkyl polyglucosides, alkanolamides and mixtures thereof.
35. A skin cleansing bar product according to claim 31 wherein said soap of animal or vegetable origin are selected from the group consisting of sodium tallowate, sodium palmate, sodium cocoate, sodium stearate, sodium palm kernelate, as a processing aid agent and hardener
36. A skin cleansing bar product according to claim 31 wherein said binders and plasticizers are selected from the group consisting cetostearyl alcohol, paraffin wax, stearic acid, palmitic acid, myristic acid, wherein said plasticizers have a melting point from about 30 to 90 ° C.
37. A skin cleansing bar product according to claim 31 wherein said moisturizing agents and emollients are selected from the group consisting of stearic acid, cetostearyl alcohol, mineral oil, vegetable oil, urea, glycerine, propylene glycol, lactic acid, sodium lactate, polyols and mixtures thereof.
38. A skin cleansing bar product according to claim 31 wherein said binding agents and processing aid agents are selected from the group consisting of maltodextrin, dextrin, starch, talc and mixtures thereof.
39. A skin cleansing bar product according to claim 31 wherein said antimycotic agent is selected from the group consisting of Clotrimazole and Miconazole.
40. A skin cleansing bar product according to claim 31 wherein said Ph adjusting acid agents are selected from the group consisting of lactic acid, phosphoric acid, citric acid, fumaric acid, tartaric acid and mixtures thereof.
41. A skin cleansing bar product according to claim 31 wherein said skin substantivity increasing agents are slected from the group consisting of quaternized polymers, sodium acrylate copolymers, cationic copolymers and mixtures thereof.
42. An antmycotic combination bar according to claim 1 comprising:
20-50% anionic surfactants;
0-20% soap;
0-10% nonionic surfactants;
0-10% amphoteric surfactants;

10-50% moisturizers, plasticizers;

10-30% binding and processing aid agents;

0.2-5% Clotrimazole or Miconazole; and

5-13% water.

43. An antimycotic combination bar according to claim 42 comprising:

30-45% anionic surfactants;

6-8% soap;

1-4% nonionic surfactants;

2-4% amphoteric surfactants;

15-35% moisturizers, emollients, plasticizers;

15-25% binding and processing aid agents;

0.5-2% Clotrimazole or Miconazole; and

6-10% water

44. A skin cleansing composition according to claim 42, which further comprises deionised water in an amount of between 5% and 13% (m/m).

45. A skin cleansing product according to claim 1 whenever produced by extrusion.

46. A process for the preparation of antimycotic solid skin cleansing products as defined in any of the preceeding claims which comprises melting together all the ingredients except the antimycotic, cooling the mixture to about 50-65°C, adding the antimycotic and extruding or casting the product into a desired shape.

47. A process for preparing antimycotic solid compositions of matter as defined in any of the preceeding claims which comprises melting together all the ingredients except the antimycotic, cooling the mixture to about 50-65°C, adding the imidazole and extruding or casting the product into a desired shape.

48. A liquid soap composition, containing:

0-25% of anionic surfactants;

0-10% of non-ionic surfactants;

0-10% of amphoteric and cationic surfactants;

0-8% of emollients and moisturizing agents;

0-10% of foam boosters and viscosity improvers;

0.2-3% of antimycotic agent;
0-5% pH adjusting acid agent;
0-1% fragrance, dye q.s; and
50-85% deionized water.

49. A liquid soap composition according to claim 48 wherein said anionic surfactants are selected from the group consisting of sodium/triethanolamine alkyl sulfates (C_{10}-C_{18}), sodium laureth sulfates, disodium lauryl ethoxy sulfosuccinates (C_{10}-C_{18}), sodium/ammonium cocoyl isethionate, sodium alkyl sulfoacetate and mixtures thereof.

50. A liquid soap composition according to claim 48 wherein said non-ionic surfactants are selected from the group consisting of alkyl polyglucosides, polymeric quaternary ammonium salt (polyquaternium), glycol distearate, cocamide DEA, glyceryl esters and mixtures thereof.

51. A liquid soap composition according to claim 48 wherein said amphoteric and cationic surfactants are selected from the group consisting of imidazoline type and betaine type surfactants.

52. A liquid soap composition according to claim 48 wherein said amphoteric and cationic surfactants are selected from the group consisting of disodium cocamphodiacetate and alkylamidopropyl betaine and alkyl betaine.

53. A liquid soap composition according to claim 48 wherein said emollients and moisturizing agents are selected from the group consisting of mineral oil, vegetal oil, silicone oil derivatives (such as dimethicone copolyol), glycerine, propylene glycol, sodium/ammonium lactate, lactic acid, urea and mixtures thereof.

54. A liquid soap composition according to claim 48 wherein said foam boosters and viscosity improvers are selected from the group consisting of cocamides, ethoxylate fatty alcohols, sodium chloride and mixtures thereof.

55. A liquid soap composition according to claim 48 wherein said antimycotic agent is selected from the group consisting of a terbinafine or ciclopirox and an imidazole.

56 A liquid soap composition according to claim 55 wherein said imidazole is selected from the group consisting of clotrimazole and miconazole.

57. A liquid soap composition according to claim 48 wherein said pH adjusting acid agents are selected from the group consisting of citric acid, lactic acid, phosphoric acid, fumaric acid, tartaric acid and mixtures thereof.

58. An antimycotic liquid soap comprising:
5-25% Anionic surfactants;
0-10% Amphoteric and cationic surfactants;
0-10% Nonionic surfactants;
1-8% Moisturizers and emollients;
0.2-3% an antimycotic agent; and
70-85% water.

59. An antimycotic liquid soap comprising:
8-12% Anionic surfactants;
1-4% Amphoteric and cationic surfactants;
2-6% Nonionic surfactants;
0.5-2% Moisturizers and emollients;
0.5-2% an antimycotic agent; and
76-82% water.

AMENDED CLAIMS

[Received by the International Bureau on 18 MAR 2004 (18.03.04) ; original claim 1, amended ; original claims 3, 4, 45 and 48-59 deleted]

WHAT IS CLAIMED IS:

1. An extruded, medicated, skin cleansing bar product for treatment or prevention of skin disorders comprising a synthetic surfactant and a single antimycotic as the sole active ingredient therein, said skin cleansing bar product having a pH of between 5.0-8.0.
2. A medicated skin cleansing product according to claim 1 further comprising up to 20% soap.
3. A product according to claim 1 which possesses good foaming qualities when dissolved in water and good foaming performance under practical usage.
4. A product according to claim 1 wherein said antimycotic is selected from the group consisting of Clotrimazole, Miconazole, Metronidazole, Bifonazole, Ketoconazole, Terconazole, Econazole Terbinafine and Ciclopirox.
5. A product according to claim 1, wherein the concentration of said antimycotic is between 0.1-5%.
6. A skin cleansing composition for the treatment or prevention of skin disorders according to claim 1 wherein said antimycotic is selected from the group consisting of Clotrimazole and Miconazole, and the concentration thereof is between 0.5-2.0%.
7. A medicated product according to claim 1 for the treatment or prevention of skin disorders containing an antimycotic and having a pH between 5.0-8.0 and further comprising up to 20% soap, wherein the skin disorder is selected form the group consisting of mycotic, fungal, itching, rash, dermatitis, tinea crusis, body tinea, eczema, pruritus and dermatophytosis.
8. A skin cleansing bar product according to claim 1 comprising:

   20-70% of anionic surfactants;

   0-10% of amphoteric and cationic surfactants;

   0-10% of nonionic surfactants;

   2-20% of binders and plasticizers, wherein said plasticizers have a melting point from about 30 to 90 ° C;

   5-30% of moisturizing agents and emollients;

   10-30% of bind and processing aid agents;

   0.2%-5% of antimycotic agent;

   0.5%-5% of skin substantivity increasing agents; and

0.2-5% of pH adjusting acid agents.

9. A skin cleansing bar product according to claim 8 wherein said anionic surfactants are selected from the group consisting of disodium alkyl sulfosuccinates (C_{10}-C_{18}), sodium/potassium long chain alkyl sulfate (C_{10}-C_{20}), sodium cocoyl isethionate, sodium alkyl sulfoacetate, acyl taurates, acyl sarcosinates, acyl glutamate, alkyl glyceryl ether sulfonates, and mixtures thereof.
10. A skin cleansing bar product according to claim 8 wherein said amphoteric and cationic surfactants are selected from the group consisting of alkylamido propyl betaine, alkyl betaine, alkyl sultaines, alkyl amine oxides and imidazolines and mixtures thereof.
11. A skin cleansing bar product according to claim 8 wherein said non-ionic surfactants are selected from the group consisting of alkyl polyglucosides, polyalkylene glycols, glyceryl monostearate, polyetoxylated fatty alcohols, polyhydroxy fatty acid amides and alkanolamides and mixtures thereof.
12. A skin cleansing bar product according to claim 8 wherein said binders and plasticizers are selected from the group consisting of cetostearyl alcohol, paraffin wax, stearic acid, palmitic acid, myristic acid, polyol esters, polyethylene glycols, fatty acid ethoxylate and mixtures thereof.
13. A skin cleansing bar product according to claim 8 wherein moisturizing agents and emollients are selected from the group consisting of stearic acid, cetostearyl alcohol, mineral oil, vegetable oil, urea, glycerine, propylene glycol, lactic acid, sodium lactate, and polyols and mixtures thereof.
14. A skin cleansing bar product according to claim 8 wherein said binding and processing aid agents are selected from the group consisting of maltodextrin, dextrin, starch and talc and mixtures thereof.
15. A skin cleansing bar product according to claim 8 wherein said pH adjusting agents are selected from the group consisting of lactic acid, phosphoric acid, citric acid, fumaric acid and tartaric acid and mixtures thereof.
16. A skin cleansing bar product according to claim 8 wherein said skin substantivity increasing agents are selected from the group consisting of quaternized polymers, sodium acrylate copolymers and cationic copolymers and mixtures thereof.

17. A skin cleansing bar product according to claim 8 wherein said antimycotic agent is selected from the group consisting of Clotrimazole and Miconazole.

18. An antifungal soap-free cleansing bar according to claim 1, comprising:
20-70% anionic surfactants;
0-10% amphoteric surfactants;
0-10% nonionic surfactants;
10-50% moisturizers, emollients, plasticizers;
10-30% binding and processing aid agents;
0.2-5% Clotrimazole or Miconazole; and
3-10% water.

19. An antifungal soap-free cleansing bar according to claim 18 comprising:
30-50% anionic surfactants;
2-4% amphoteric surfactants;
1-4% nonionic surfactants;
15-35% moisturizers, emollients, plasticizers;
15-25% binding and processing aid agents;
0.5-2% Clotrimazole or Miconazole; and
5-8% water.

20. A skin cleansing composition according to claim 1 which further comprises stearic acid in an amount effective to serve as a moisturizing agent and/or emollient.

21. A skin cleansing composition according to claim 20, in which the stearic acid is present in a concentration of between 5 and 30%.

22. A skin cleansing composition as claimed in any one of the preceding claims, which further comprises glycerin in an amount effective to serve as a lubricating and moisturizing agent.

23. A skin cleansing composition according to claim 22, in which the glycerin is present in a concentration of between 0.5 and 5%.

24. A skin cleansing composition according to claim 22, in which the glycerin is present in an amount of 2%.

25. A skin cleansing composition according to claim 1, which further comprises propylene glycol in an amount effective to serve as a solvent for the components forming part of the composition.

26. A skin cleansing composition according to claim 25, in which the propylene glycol is present in a concentration of between 0.5% and 5%.
27. A skin cleansing composition according to claim 25, in which the propylene glycol is present in an amount of 1%.
28. A skin cleansing composition according to claim 1, which further comprises deionised water in an amount of between 3% and 10% (m/m).
29. A skin cleansing combination bar composition according to claim 1 comprising:

i) 20-50% of anionic surfactants;
ii) 0-10% of amphoteric and cationic surfactants;
iii) 0-10% of nonionic surfactants;
iv) 0.1-20% of soap, of animal or vegetable origin;
v) 2-20% of binders and plasticizers;
vi) 5-30% of moisturizing agents and emollients;
vii) 10-30% of binding agents and processing aid agents;
viii) 0.2%-5% of antimycotic agent;
ix) 0.5%-5% of skin substantivity increasing agents; and
x) 0.2-5% of pH adjusting acid agents

30. A skin cleansing combination bar product according to claim 29 wherein said anionic surfactants are selected from the group consisting of disodium alkyl sulfosuccinates (C_{10}-C_{18}), sodium/potassium long chain alkyl sulfate (C_{10}-C_{20}), sodium cocoyl isethionate, sodium alkyl sulfoacetates, acyl taurates, acyl sarcosinates, acyl glutamates, alkyl glyceryl ether sulfonates, and mixtures thereof.
31. A skin cleansing bar product according to claim 29 wherein said amphoteric and cationic surfactants are selected from the group consisting of alkylamido propyl betaine, alkyl betaine, imidazolines and mixtures thereof.
32. A skin cleansing bar product according to claim 29 wherein said nonionic surfactants are selected from the group consisting of glyceryl monostearate, polyalkylene glycols, polyetoxylated fatty alcohos, polyhydroxy fatty acid amides, alkyl polyglucosides, alkanolamides and mixtures thereof.
33. A skin cleansing bar product according to claim 29 wherein said soap of animal or vegetable origin are selected from the group consisting of sodium

tallowate, sodium palmate, sodium cocoate, sodium stearate, sodium palm kernelate, as a processing aid agent and hardener

34. A skin cleansing bar product according to claim 29 wherein said binders and plasticizers are selected from the group consisting cetostearyl alcohol, paraffin wax, stearic acid, palmitic acid, myristic acid, wherein said plasticizers have a melting point from about 30 to 90 ° C.

35. A skin cleansing bar product according to claim 29 wherein said moisturizing agents and emollients are selected from the group consisting of stearic acid, cetostearyl alcohol, mineral oil, vegetable oil, urea, glycerine, propylene glycol, lactic acid, sodium lactate, polyols and mixtures thereof.

36. A skin cleansing bar product according to claim 29 wherein said binding agents and processing aid agents are selected from the group consisting of maltodextrin, dextrin, starch, talc and mixtures thereof.

37. A skin cleansing bar product according to claim 29 wherein said antimycotic agent is selected from the group consisting of Clotrimazole and Miconazole.

38. A skin cleansing bar product according to claim 29 wherein said Ph adjusting acid agents are selected from the group consisting of lactic acid, phosphoric acid, citric acid, fumaric acid, tartaric acid and mixtures thereof.

39. A skin cleansing bar product according to claim 29 wherein said skin substantivity increasing agents are slected from the group consisting of quaternized polymers, sodium acrylate copolymers, cationic copolymers and mixtures thereof.

40. An antmycotic combination bar according to claim 1 comprising:

20-50% anionic surfactants;

0-20% soap;

0-10% nonionic surfactants;

0-10% amphoteric surfactants;

10-50% moisturizers, emollients, plasticizers;

10-30% binding and processing aid agents;

0.2-5% Clotrimazole or Miconazole; and

5-13% water.

41. An antimycotic combination bar according to claim 40 comprising:
30-45% anionic surfactants;
6-8% soap;
1-4% nonionic surfactants;
2-4% amphoteric surfactants;
15-35% moisturizers, emollients, plasticizers;
15-25% binding and processing aid agents;
0.5-2% Clotrimazole or Miconazole; and
6-10% water

42. A skin cleansing composition according to claim 40, which further comprises deionised water in an amount of between 5% and 13% (m/m).

43. A process for the preparation of antimycotic solid skin cleansing products as defined in any of the preceeding claims which comprises melting together all the ingredients except the antimycotic, cooling the mixture to about 50-65°C, adding the antimycotic and extruding the product into a desired shape.

44. A process for preparing antimycotic solid compositions of matter as defined in any of the preceeding claims which comprises melting together all the ingredients except the antimycotic, cooling the mixture to about 50-65°C, adding the imidazole and extruding the product into a desired shape.

INTERNATIONAL SEARCH REPORT

Intern ation No
PCT/IL 03/00739

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K7/50

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)
IPC 7 A61K

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, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	page 6, line 17-20; claims 1-8	10-21, 31-47

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Y	examples 13,14	10-21, 31-47

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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