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(54) Title: A SOAP COMPOSITION

(57) Abstract: A soap composition comprising 10 % to 80 weight % of a soap, 1 % to 60 weight % of a clay belonging to the smectite group, 0.01 % to 2 % of 3,4,4' trichlorocarbaniide (TCC), and 0.01 % to 2 % of 4,2',4' - trichloro-2-hydroxy diphenyl ether (TCN).



WO 2006/097238 A1

- 1 -

A SOAP COMPOSITION

The invention relates to a synergistic soap composition that provides anti-acne benefit in personal washing.

5

Conventional detergent bars, based on soap for personal washing contain over about 70 % by weight total fatty matter (TFM), the remainder being water (about 10 % to 20 %) and other ingredients such as colour, perfume, preservatives, etc. Structurants and fillers are also present in such compositions in small amounts that replace some of the soap in the bar while retaining the desired hardness of the bar. The commonly used fillers include starch, kaolin and talc. Cleansing compositions are formulated in various forms such as bars, liquids, gels, pastes, etc.

Acne is a condition of the skin, which is highly undesirable, especially among the younger population. The cause of acne and its prevention/cure has been widely studied. Internal physiology including hormone levels in the body, the general cleanliness of the skin, the rate of sebum generation, accumulation and removal, the activity of microbial entities, e.g. bacteria, and the weather conditions, e.g. the ambient temperature and humidity, have all been implicated to varying degrees in the phenomena of acne. Sebum is produced by sebaceous glands on the skin and is a mixture of fats, waxes etc. Its function is generally to provide a moisture barrier on the skin.

The literature is replete with methods and compositions for eliminating, treating or at least reducing the levels of

- 2 -

acne. Various leave on, wash off and face pack type of products have been formulated for the purpose. The predominant microbe implicated in acne is the *P. Acnes*, though few reports implicate *Staphylococcus aureus* (*S.*
5 *aureus*), *S. epidermidis*, *S. pyogens*, and *Malaseszzia furfur*. The traditional hypothesis is that *P. Acnes* degrades sebum to produce free fatty acids which are irritants and lead to an inflammatory response.

10 Use of anti-bacterial agents is one of the preferred routes for alleviation of the condition of acne. Some work has been done on the use of anti-bacterials in wash-off products. Various types of clays have also been suggested both in leave-on type compositions, e.g. face-packs for
15 reducing the oiliness of the skin, and also in wash-off compositions.

US 4118332 (Colgate-Palmolive, 1978) describes an anti-bacterial detergent composition comprising (1) a diphenyl
20 ether compound and (2) at least one compound selected from the group consisting of 3,4,4'-trichlorocarbanilide and 3,3', 4-trichlorocarbanilides the ratio of (1) to (2) being from 1:3 to 3:1.

25 US 5062994 (Diana Imperatori, 1991) describes a moisture-free skin cleansing composition in tablet form comprising a skin cleansing powder selected from certain anionic or non-ionic surface active agents, and at least one absorbing powder selected from the group consisting of cellulose,
30 modified starches, kaolin, bentonite, talc, silicates,

- 3 -

silica, magnesium carbonates, magnesium hydroxides, attapulgite, montmorillonite and mixtures thereof, a lubricating material and a disaggregating substance.

- 5 JP10-212489 (Kanebo, 1998) describes a cleaning composition comprising one or more anionic surfactant having two chains and two polar groups containing amido groups, and 0.002-5wt.% microbicide of one or more compounds selected from 2,4,4'-trichloro-2-hydroxydiphenyl ether, 3,4,4'-trichlorocarbanilide, benzethonium chloride, zinc bis(2-pyridylthio)-N-oxide, piroctoneolamin, photosensitive materials, a C8-22 unsaturated fatty acid such as undecylenic acid and sulfur, and preferably 1 % to 40wt.% clay mineral.
- 15 JP 63139998 (Lion Corporation) describes a skin detergent composition containing an anionic surfactant, 0.001 % to 5 wt.% of a disinfectant 1 % to 50 % of a clay mineral. The disinfectant is one or a mixture of 2,4,4'-trichloro-2'-hydroxydiphenyl ether, 3,4,4'-trichloro carbanilide, pyroctone oramine, sensitising dyes, C8-22 unsaturated fatty acids such as undecylenic acid and sulphur. The clay mineral has a laminated structure of $(Si_2O_5(2-))$, and grain sizes of 0.05-30 microns. Suitable surfactants include
- 20 sodium and potassium salts of fatty acids.
- 25

Traditionally, various clays have been topically applied to provide skin benefits. It has now been found by the present inventors that use of a clay belonging to the smectite class

30 of compounds along with a selective combination of

- 4 -

antibacterial agents, viz. 3,4,4' trichlorocarbanilide (TCC) and 4,2',4'-trichloro-2-hydroxy diphenyl ether (TCN), and a soap in a washing composition provides synergistic benefit for control of acne. This specific combination surprisingly provides benefits far superior to a composition that does not contain the selective clay, or when only one of the anti-bacterials agent is present.

It is thus an object of the present invention to be able to provide for a personal wash soap composition that provides synergistic benefit in controlling acne.

It is another object of the present invention to be able to provide a personal wash soap composition comprising a clay and an anti-bacterial agent which are readily and inexpensively available, and therefore enables production of cleansing compositions at low cost.

Thus according to a first aspect of the present invention, there is provided a soap composition comprising:

- 5 to 80 weight % of a soap;
- 1 to 60 weight% of a clay belonging to the smectite group;
- 0.01 to 2% of 3,4,4' trichlorocarbanilide (TCC);
- 0.01 to 2% of 4,2',4' - trichloro-2-hydroxy diphenyl ether (TCN); and optionally other conventional ingredients.

- 5 -

It is particularly preferred that the clay belonging to the smectite group is bentonite, and more preferably sodium bentonite.

- 5 The invention is particularly directed to a personal wash soap composition comprising soap, a clay belonging to the smectite group and a selective combination of TCC and TCN in reducing incidence of acne.
- 10 The composition of the invention comprises soap. The term soap denotes salts of carboxylic fatty acids. The soap may be derived from any of the triglycerides conventionally used in soap manufacture - consequently the carboxylate anions in the soap may contain from 8 to 22 carbon atoms. The term
- 15 total fatty matter, usually abbreviated to TFM, is used to denote the percentage by weight of fatty acid and triglyceride residues present in soaps, without taking into account the accompanying cations.
- 20 For a soap having 18 carbon atoms, an accompanying sodium cation will generally amount to about 8 % by weight. Other cations may be employed as desired, such as for example zinc, potassium, magnesium, alkyl ammonium and aluminium.
- 25 The soap may be obtained by saponifying a fat and/or a fatty acid. The fats or oils generally used in soap manufacture may be such as tallow, tallow stearines, palm oil, palm stearines, soya bean oil, fish oil, castor oil, rice bran oil, sunflower oil, coconut oil, babassu oil, palm kernel
- 30 oil, and others. In the above process the fatty acids are derived from oils/fats selected from coconut, rice bran,

- 6 -

groundnut, tallow, palm, palm kernel, cotton seed, soybean, castor etc. The fatty acid soaps can also be synthetically prepared (e.g. by the oxidation of petroleum, or by the hydrogenation of carbon monoxide by the Fischer-Tropsch process). Resin acids, such as those present in tall oil, may be used. Naphthenic acids are also suitable.

Tallow fatty acids can be derived from various animal sources and generally comprise about 1 % to 8 % myristic acid, about 21 % to 32 % palmitic acid, about 14 % to 31 % stearic acid, about 0 to 4 % palmitoleic acid, about 36 % to 50 % oleic acid and about 0 to 5 % linoleic acid. A typical distribution is 2.5 % myristic acid, 29 % palmitic acid, 23 % stearic acid, 2 % palmitoleic acid, 41.5 % oleic acid, and 3 % linoleic acid. Other similar mixtures, such as those from palm oil and those derived from various animal tallow and lard, are also included.

Coconut oil refers to fatty acid mixtures having an approximate carbon chain length distribution of 8 % C8, 7 % C10, 48 % C12, 17 % C14, 8 % C16, 2 % C18, 7 % oleic and 2 % linoleic acids (the first six fatty acids listed being saturated). Other sources having similar carbon chain length distributions, such as palm kernel oil and babassu kernel oil, are included within the term coconut oil.

A typical fatty acid blend consisted of 5 % to 30 % coconut fatty acids and 70 % to 95 % fatty acids ex hardened rice bran oil. Fatty acids derived from other suitable oils/fats such as groundnut, soybean, tallow, palm, palm kernel, etc. may also be used in other desired proportions.

- 7 -

The composition according to the invention may optionally comprise non-soap detergent actives, which are generally chosen from anionic, nonionic, cationic, amphoteric or zwitterionic detergent actives. It is preferred that if
5 non-soap detergents are used in the composition of the invention, the non-soap detergent is chosen from anionic or non-ionic detergent active.

The composition of the invention also comprises a clay
10 belonging to the smectite group of clays. Smectites constitute a group in the class of natural aluminosilicate minerals known as phyllosilicates or layer silicates. Other groups in this class include micas, kaolins, vermiculites, chlorites, talc and pyrophyllite. The phyllosilicate
15 structure consists of layers in which planes of oxygen atoms coordinate to cations such as Si, Al, Mg and Fe to form two-dimensional sheets. The coordination of cations in adjacent sheets typically alternates between tetrahedral and octahedral.

20

Smectites are characterized by a 2:1 layer structure in which two tetrahedral sheets form on either side of an octahedral sheet through sharing of apical oxygens. As the apical oxygens from the tetrahedral sheet form ditrigonal or
25 hexagonal rings, one oxygen from the octahedral sheet is located on the centre of each ring and is protonated to yield a structural hydroxyl. In 2:1 phyllosilicates, isomorphous substitution of cations having different valencies can lead to charge imbalances within a sheet.
30 These may be partly balanced by the opposite type of charge imbalance in the adjacent sheet (eg., a positively charged

- 8 -

octahedral sheet may offset some of the negative charge associated with a tetrahedral sheet). The net charge imbalance on a 2:1 layer, if it occurs, is negative. This charge is referred to as the *layer charge* of the mineral, and is balanced by larger cations (eg., Na^+ , K^+ , Ca^{+2} and Mg^{+2}) that coordinate to the basal surfaces of the tetrahedral sheets from the adjacent layers. Since these charge-balancing cations are located between adjacent 2:1 layers, they are referred to as "interlayer cations". The 2:1 phyllosilicates are distinguished chiefly on the basis of their layer charge.

The compounds/clay materials belonging to the class of smectites is quite large, and, especially, the Cs exchanged classes of smectites include hectorite, saponite, and montmorillonite, in addition to vermiculite, and, several non-exchangeable phyllosilicates.

The preferred clays as per this invention are sodium and calcium montmorillonite, which are part of the smectite group of natural aluminosilicate minerals and are the most common members. Montmorillonite is the major phase in a type of clays called bentonites. Amongst the calcium and sodium bentonites, sodium bentonite is more preferred.

Clay is preferably present at a concentration of 2 % to 40 %, more preferably at a concentration of 5 % to 30 % by weight of the composition.

- 9 -

TCC, 3,4,4' trichlorocarbanilide is a known antimicrobial agent, and is also known as Triclocarban. It is also known by the chemical name 1-(3',4'-dichlorophenyl)-3-(4'-chlorophenyl) urea. TCC is preferably present in the composition at 0.01 % to 2 %, more preferably at 0.05 % to 1 % by weight of the composition.

TCN, 4,2',4' - trichloro-2-hydroxy diphenyl ether, is a known anti-microbial agent that has been used extensively in oral care compositions, and is also known by the tradename Triclosan. TCN is preferably present in the composition at 0.01 % to 2 %, more preferably at 0.05 % to 1 % by weight of the composition.

Conventional benefit agents e.g. moisturisers, emollients, sunscreens, or anti-ageing compounds, may be incorporated in the composition of the invention. Examples of moisturisers and emollients include humectants like polyols, glycerol, cetyl alcohol, carbopol, ethoxylated castor oil, paraffin oils, lanolin and its derivatives. Silicone compounds such as silicone surfactants like DC3225C (Dow Corning) and/or silicone emollients, silicone oil (DC-200 Ex-Dow Corning) may also be included. Sun-screens such as 4-tertiary butyl-4'-methoxy dibenzoylmethane (available under the trade name PARSOL 1789TM) and/or 2-ethyl hexyl methoxy cinnamate (available under the trade name PARSOL MCXTM) or other UV-A and UV-B sun-screens may also be incorporated. Water-soluble glycols such as propylene glycol, ethylene glycol, and glycerol may be employed, at levels up to 10 %.

- 10 -

Other additives such as one or more water insoluble particulate materials e.g. polysaccharides such as starch or modified starches and cellulose may be incorporated. Minor additives include colour, preservatives and perfumes, may
5 optionally be incorporated.

The composition according to the present invention can be prepared by either the extrusion or cast route. The invention is carried out in any mixer conventionally used in
10 soap/detergent manufacture, and is preferably a high shear-kneading mixer. The clays according to the invention can be incorporated into the soap or detergent active at any point in the process.

15 The details of the invention, its objects and advantages are explained hereunder in greater detail in relation to non-limiting exemplary illustrations.

EXAMPLES

20

Example 1

A soap bar according to the invention was prepared with 60 % soap, 16.5 % sodium bentonite, 0.3 % TCC and 0.3 % TCN.

25

Comparative Example A

A commercial sample of a soap bar which contained 60 % soap and 16.5 % talc was prepared as a control sample. This
30 sample did not contain any clay or anti-bacterial

- 11 -

Comparative Example B

A sample as per Comparative Example B was prepared, except that 0.3 % TCC, 0.3 % TCN was added to it while no clay was present.

Efficacy trials

A parallel arm, double-blinded, dermatologist-controlled clinical trial was carried out with 40 volunteers per cell using one product over a course of 12 weeks (total 120 volunteers for three products). The trial consisted of the volunteers using samples which were coded, and so the volunteers were not aware as to the contents of the sample. Samples of Example 1, Comparative Example A and Comparative Example B were tested. The volunteers were asked to note the perceived reduction or increase in oiliness and incidents of acne at the end of every two weeks. The data is summarized in Table 1.

Table 1

Week	Example 1			Comparative Example A			Comparative Example B		
	Red (oil)	Red. (Acne)	Incr. (Acne)	Red. (oil)	Red. (Acne)	Incr. (Acne)	Red. (oil)	Red. (Acne)	Incr. (Acne)
2	84	91	0	69	50	18	63	43	25
4	85	73	12	46	59	26	47	43	21
6	79	70	8	23	39	18	48	55	28
8	70	70	27	24	53	25	53	47	26
10	33	73	17	29	53	29	21	53	29
12	43	68	24	32	43	23	57	39	48

- 12 -

Red. Indicates the percentage of volunteers who perceived a reduction in the incidence of acne or oiliness.

Incr. Indicates the percentage of volunteers who perceived
5 an increase in the incidence of acne.

The data presented in Table 1 shows that the composition as per the invention (Example 1) is perceived by a significantly higher percentage of the volunteers who tested
10 the products to produce a reduction both in terms of oiliness of the skin and the incidence of acne, as compared to the compositions outside the scope of the invention (Comparative Examples A and B), over a prolonged period of
15 time.

- 13 -

CLAIMS

1. A soap composition comprising:

10 % to 80 weight % of a soap;

5 1 % to 60 weight % of a clay belonging to the smectite group;

0.01 to 2% of 3,4,4' trichlorocarbanilide (TCC); and

0.01 to 2% of 4,2',4' - trichloro-2-hydroxy diphenyl ether (TCN).

10

2. A soap composition as claimed in claim 1, wherein the clay belonging to the smectite group is a bentonite, preferably selected from calcium or sodium bentonite.

15 3. A soap composition as claimed in claim 2, wherein the clay belonging to the smectite group is sodium bentonite.

4. A soap composition according to any one of the preceding
20 claims, wherein the clay is a monmorillonite, preferably calcium or sodium montmorillonite.

5. A soap composition according to any one of the preceding
25 claims, wherein the clay is present in the composition at a level of 2 % to 40 % by weight of the composition.

6. A soap composition as claimed in claim 5, wherein the clay is present at 5 % to 30 % by weight of the composition.

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- 14 -

7. A soap composition as claimed in any one of the preceding claims, wherein TCC is present in an amount in the range of 0.05 % to 1 % by weight of the composition.
- 5 8. A soap composition as claimed in any one of the preceding claims, wherein TCN is present in an amount in the range of 0.05 % to 1 % by weight of the composition.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

INV. C11D9/18 C11D9/50 A61Q19/10

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)

C11D 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, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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