COMPOSITIONS COMPRISING NONIONIC AND ZWITTERIONIC SURFACTANTS

BACKGROUND OF THE INVENTION

[0001] Foaming agents containing anionic surfactants, such as sodium lauryl sulfate, sodium laureth sulfate, and sodium methyl cocoyl taurate have traditionally been used in consumer care products, oral products, e.g., dentifrices, due to their low cost and ability to foam. The foaming ability of a consumer product is important in that consumers correlate the foaming ability with the effectiveness of the product. However, many people suffer from adverse reactions to anionic surfactants. For example, anionic surfactants tend to irritate the oral cavity, and may cause discomfort and irritation, especially in patients suffering from various oral conditions, e.g., xerostomia and/or tooth sensitivity. Such irritation is especially undesirable, especially in people suffering from, or predisposed to various conditions, such as xerostomia (dry mouth). Current products used for the treatment of dry mouth require high concentrations of fluoride to lower their risk of developing caries. However, such products may not recognize that the ingredients contained therein may cause irritation of the oral cavity, and thus exacerbate xerostomia.

[0002] Removing anionic surfactants from consumer products reduces their ability to produce foam. As previously stated, the ability of a product to foam is important in that consumers may correlate the foaming ability of a composition with its efficacy. Moreover, the foam produced by an oral care product may containing active ingredients, and the foam allows for the active ingredient to permeate throughout the oral cavity, including areas between teeth which are not accessible by brushing alone. Previous attempts to develop anionic surfactant free consumer products which produce an acceptable quality and quantity of foam has failed, as surfactants are incompatible with the product, or the rheology of the product must be modified in order to incorporate replacement surfactants. In many cases, such modifications render the composition unsuitable for its intended use.

[0003] Thus, there is a need to develop anionic surfactant free foaming agents. There is also a need to develop oral products which do not contain irritating ingredients, or reduces irritating ingredients present in the composition. Such compositions may be utilized to treat and/or alleviate xerostomia.

BRIEF SUMMARY OF THE INVENTION

[0004] The present invention is directed to the suprising discovery that a foaming agent comprising nonionic and zwitterionic surfactants may be used to replace foaming agents

containing anionic surfactants. Thus, the present invention is directed in part to a foaming agent comprising a non-ionic surfactant, a zwitterionic surfactant, and is free of anionic surfactants. The foaming agent may be used in any number of personal care products, such as oral products, e.g., dentifrice compositions. The ability for such compositions to foam is equivalent to, or may even be superior to similar compositions containing one or more anionic surfactants.

[0005] Thus, present invention is directed to Foaming Agent 1.0, comprising a non-ionic surfactant and a zwitterionic surfactant.

[0006] Additional embodiments of the present invention include the following compositions:

1.1. Foaming agent 1.0 free of anionic surfactants, e.g., SDS, SLS, or sodium methylcocoyl taurate;

1.2. Foaming agent 1.0 or 1.1 free of anionic surfactants;

1.3. Any of the preceding foaming agents wherein the non-ionic surfactant is a poly(oxyethylene)-poly(oxypropylene) copolymer;

1.4. Any of the preceding foaming agents comprising from about 0.1% to about 20% of a non-ionic surfactant, e.g., from about 0.5% to about 10%, about 1%, about 2%, or about 3%;

1.5. Any of the preceding foaming agents wherein the zwitterionic surfactant is an amido betaine;

1.6. Any of the preceding foaming agents wherein the zwitterionic surfactant is cocoamidoethyl betaine, cocoamidopropyl betaine, lauramidopropyl betaine, or combinations thereof;

1.7. Any of the preceding foaming agents wherein the zwitterionic surfactant is cocoamidopropyl betaine.

1.8. Any of the preceding foaming agents comprising from about 0.1% to about 10% of a zwitterionic surfactant, e.g., about 0.2 – 5%, about 0.4%, about 0.5%, about 0.6%, or about 1%;

1.9. Any of the preceding foaming agents which produces an equivalent quantity of foam compared to a comparison agent which comprises an anionic surfactant and is substantially free of non-ionic and zwitterionic surfactants;

1.10. Any of the foaming agents which produces an equivalent quality of foam compared to a comparison agent which comprises an anionic surfactant and is substantially free of non-ionic and zwitterionic surfactants;

1.11. Foaming agents 1.9 and 1.10 wherein the comparison agent comprises about 1.2% sodium methyl cocoyl taurate.

[0007] The present invention is also directed to Composition 2.0, a dentifrice composition comprising any one of foaming agents 1.0 – 1.11.

[0008] The present invention is also directed to the following compositions:

2.1 Any of the preceding compositions further comprising a fluoride ion source, e.g., sufficient to provide from about 250 ppm to about 25,000 ppm fluoride ions, e.g., about 1000 ppm to about 1500 ppm, about 1250 ppm, 1500 ppm, or about 5000 ppm fluoride ions.

2.2 Composition 1.9 wherein the fluoride ion source is sodium fluoride, potassium fluoride, calcium fluoride, zinc fluoride, zinc ammonium fluoride, lithium fluoride, ammonium fluoride, stannous fluoride, stannous fluorozirconate, sodium monofluorophosphate, potassium monofluorophosphate, laurylamine hydrofluoride, diethylaminoethyloctoylamide hydrofluoride, didecyldimethylammonium fluoride, cetylpyridinium fluoride, dilaurylmorpholinium fluoride, sarcosine stannous fluoride, glycine potassium fluoride, glycine hydrofluoride, amine fluorides, or combinations thereof;

2.3 Any of the preceding compositions comprising an effective amount of a desensitizing agent;

2.4 Any of the preceding compositions comprising a potassium salt, capsaicin, eugenol, a strontium salt, a zinc salt, a chloride salt, or combinations thereof;

2.5 Any of the preceding compositions comprising potassium nitrate, potassium bicarbonate, potassium chloride, potassium citrate, potassium oxalate, or combinations thereof;

2.6 Any of the preceding compositions comprising an effective amount of an antibacterial agent;

2.7 Any of the preceding compositions comprising a halogenated diphenyl ether, e.g., triclosan;

2.8 Any of the preceding compositions comprising cetylpyridinium chloride;

2.9 Any of the preceding compositions comprising stannous ion agent, triclosan, triclosan monophosphate, chlorhexidine, alexidine, hexetidine, sanguinarine, benzalkonium chloride, salicylanilide, arginate esters, ethyl lauryl arginate,

bisphenols, domiphen bromide, tetradecylpyridinium chloride, N-tetradecyl-4-ethylpyridinium chloride, octenidine, delmopinol, octapinol, nisin, zinc ion agent, copper ion agent, essential oils, furanones, bacteriocins, a basic amino acid, or combinations thereof;

2.10 Any of the preceding compositions comprising silica, a humectant, a stabilizing agent, an antibacterial agent, a sweetener, a surfactant, or combinations thereof;

2.11 Any of the preceding compositions which is a dentifrice, e.g., a toothpaste;

2.12 Any of the preceding compositions comprising about 0.5% of cocoamidopropyl betaine;

2.13 Any of the preceding compositions comprising about 2% of a poly(oxyethylene)-poly(oxypropylene) copolymer;

[0009] The present invention is also directed to a method for treating and/or alleviating xerostomia comprising applying any one of compositions 2.0 – 2.13 to the oral cavity, e.g., by brushing.

[0010] Other embodiments of the present invention will be apparent to one of skill in the art.

DETAILED DESCRIPTION OF THE INVENTION

[0011] Throughout the present disclosure, ranges are used as a shorthand for describing each and every value that is within the range. Any value within the range can be selected as the terminus of the range.

[0012] In an embodiment of the present invention, a foaming agent comprising zwitterionic and non-ionic surfactants, and free of anionic surfactants is provided. Anionic surfactants are not added to the foaming agent, although some may be present due to unintended contamination, or decomposition of other ingredients, or unintended reaction between other ingredients. Anionic surfactants are known by those of skill in the art.

[0013] Zwitterionic surfactants are known in the art, and generally include surfactants which are neutrally charged overall, but carry at least one positive charged atom/group, and at least one negatively charged atom/group. Preferable zwitterionic surfactants used in the present invention are quaternary ammonium compounds and betaines, e.g, amido betaines, such as cocoamidoethyl betaine, cocoamidopropyl betaine, lauramidopropyl betaine and the like. A preferred zwitterionic surfactant for use in the present invention is the cocoamidopropyl betaine.

[0014] Non-ionic surfactants are known in the art, and generally include surfactants which are not electrically charged. A preferred nonionic surfactant may be poly(oxyethylene)-

poly(oxypropylene) block copolymers. Such copolymers are known commercially by the non-proprietary name of poloxamers. The name poloxamer is often used in conjunction with a numeric suffix to designate the individual identification of each copolymer. Poloxamers may have varying contents of ethylene oxide and propylene oxide which results in poloxamers which have a wide range of chemical structures and molecular weights. A preferred poloxamer is Poloxamer 407, sold under the trade name PLURONIC F127 by BASF, Inc. (Parsippany, N.J.).

[0015] The foaming agent may be incorporated into personal care compositions, e.g., compositions for application on the skin or oral cavity. In one embodiment, the foaming agent is incorporated into an oral care composition, which may also include a fluoride ion source, an antibacterial agent, and/or an anti-sensitivity agent. Preferably, anionic surfactants are not added to the composition, although some may be present due to unintended contamination, or decomposition of other ingredients, or unintended reaction between other ingredients.

[0016] The oral care composition is preferably in the form of a dentifrice. Preferred dentifrices include but are not limited to various types of toothpaste, tooth polish, tooth gel, mouthwash and mouth rinse, denture adhesive or cream or the like.

[0017] The oral care compositions of the present invention preferably contain fluoride ions. Fluoride ions may be provided by a fluoride ion source. A fluoride ion source may be anything that is capable of releasing fluoride ion in an aqueous environment. Typical sources include soluble salts of the fluoride ion; such as, for example: sodium fluoride, potassium fluoride, calcium fluoride, zinc fluoride, zinc ammonium fluoride, lithium fluoride, ammonium fluoride, stannous fluoride, stannous fluorozirconate, and complex fluorides, monofluorophosphates and salts thereof such as, *e.g.*, sodium monofluorophosphate or potassium monofluorophosphate, laurylamine hydrofluoride, diethylaminoethyloctoylamide hydrofluoride, didecyldimethylammonium fluoride, cetylpyridinium fluoride, dilaurylmorpholinium fluoride, sarcosine stannous fluoride, glycine potassium fluoride, glycine hydrofluoride, and amine fluorides.

[0018] The fluoride ion source is most preferably in an amount such that it is capable of maintaining a high level of fluoride ion in the composition that is at least about 250 ppm, and in some instances up to as much as about 25,000 ppm. Preferably, the fluoride ions are present in an amount of about 1000 ppm to about 1500 ppm. In order to provide such a concentration in the optimal ppm range, the exact weight percentage of the fluoride ion source in the composition may vary, depending upon the stoichiometric properties of different fluoride ion sources.

[0019] In one embodiment, an oral care composition is provided that can incorporate high levels of fluoride for anticaries treatment, tooth sensitivity, and xerostomia. The compositions may also incorporate one or more sensitivity treatment agents, e.g., potassium salts such as potassium nitrate, potassium bicarbonate, potassium chloride, potassium citrate, and potassium oxalate; capsaicin; eugenol; strontium salts; zinc salts; chloride salts and combinations thereof. Such agents may be added in effective amounts, which preferably vary between about 0.01% to about 10% by weight based on the total weight of the composition, depending on the agent chosen.

[0020] Preferably, a desensitizing agent is a potassium salt in an amount of at least about 5% by weight of a potassium salt based on the total weight of the composition. Most preferably, the composition includes about 5% to about 10% by weight of the potassium salt. Effective amounts of such potassium salts and their use are described in *e.g.*, the following patents: U.S. Patents Nos. 3,863,006, 4,631,185 and 4,751,072, the contents of which are incorporated by reference in their entirety. Most preferably, the desensitizing agent is potassium nitrate.

[0021] Other thickening agents that may be used in the oral care compositions of the present invention. Other thickening agents are known in the art, and include, but are not limited to: silica thickeners; glycerites; gums such as tragacanth, ghatti, acacia, veegum; sodium alginate; carboxymethyl cellulose; hydroxyethyl cellulose, hydroxypropyl cellulose; hydroxymethyl cellulose; hydroxymethyl carboxypropyl cellulose; methyl cellulose; ethyl cellulose; sulfated cellulose; as well as mixtures and combinations of these compounds. Such additional thickeners may be used in amounts of up to about 15 wt % of the composition based on the total weight of the composition.

[0022] The oral care compositions of the present invention may also include a variety of common additional active agents typically used in oral care formulations, including but not limited to: triclosan; triclosan monophosphate; chlorhexidine; alexidine; hexetidine; sanguinarine; benzalkonium chloride; salicylanilide; arginate esters; ethyl lauryl arginate, bisphenols, domiphen bromide; tetradecylpyridinium chloride; N-tetradecyl-4-ethylpyridinium chloride; octenidine; delmopinol; octapinol; nisin; zinc ion agent; copper ion agent; essential oils; furanones; bacteriocins; salts of the foregoing active agents and mixtures and combinations thereof.

[0023] Optional additives for the oral care compositions of the present invention may also be used, such as those commonly used for forming a dentifrice, including but not limited to: abrasives and/or amorphous silica, humectants, stabilizing agents, antibacterial agents, sweeteners, colorants, healing agents, other caries preventative agents, chelating/sequestering agents, vitamins,

amino acids, proteins, anti-plaque agents, anti-calculus agents, opacifiers, antibiotics, anti-enzymes, enzymes, pH control agents, oxidizing agents, antioxidants, whitening agents, basic amino acids (in free base or salt form) and preservatives.

[0024] One or more abrasive or polishing materials may also be included in the oral care compositions of the present invention. The abrasive or polishing material can be any material that is acceptable for use in a dentifrice, does not excessively abrade dentin and is compatible with the other components of the oral care composition. Exemplary abrasive or polishing materials include, but are not limited to: silicas, aluminas, phosphates, carbonates, and mixtures, derivatives and salts thereof, and resinous abrasive materials.

[0025] One or more humectants may be added to the oral care compositions of the present invention, for providing body or texture to the formulations and for maintaining moisture in the formulations. Useful humectants include, but are not limited to: various polymeric glycols and other hydroxy-based humectants such as, *e.g.*, propylene glycols, glycerol, erythritol, xylitol, sorbitol, mannitol, lactitol, hydrogenated starch hydrolyzates and combinations of these components.

[0026] Antibacterial agents can be used if reduction of microorganisms is desired, and can include known antibacterial agents used in dentifrice formulations such as, *e.g.*, benzoic acid, sodium benzoate, potassium benzoate, boric acid, and phenolic compounds such as betanaphthol, chlorothymol, thymol, anethole, eucalyptol, carvacrol, menthol, phenol, amylphenol, hexylphenol, heptylphenol, octylphenol, hexylresorcinol, laurylpyridinium chloride, myristylpyridinium chloride, cetylpyridinium fluoride, cetylpyridinium chloride and cetylpyridinium bromide.

[0027] Sweeteners may be used in the oral care compositions of the present invention if desired, and may include any of those commonly used in a dentifrice to impart a pleasing taste to the product. Suitable sweeteners include but are not limited to: saccharins and derivatives thereof, cyclamates and derivatives thereof, acesulfane-K, thaumatin, neohisperidin dihydrochalcone, ammoniated glycyrrhizin, dextrose, levulose, sucrose, mannose, glucose and any other suitable sweeteners.

[0028] One of skill in the art would recognize that an ingredient may serve various purposes in the composition. For example, cetylpyridinium chloride may serve as a cationic surfactant, and as an antibacterial agent. Compositions of the present invention may incorporate cetylpyridinium chloride, preferably in amounts effective as an antibacterial agent, though may also act as a surfactant.

[0029] The other ingredients noted may be any of those commonly used in dentifrice formulations and can be selected based upon the intended end use of the formulations and to optimize the physical and aesthetic characteristics of the formulations.

[0030] The foaming agent of the present invention may also be incorporated into any number of personal care compositions, e.g., lotions, creams, shampoos, conditioners, hair gel, soaps, body wash, or any other personal care product which traditionally utilizes one or more anionic surfactants. The foaming agent of the present invention may also be incorporated into any number of products used to clean a home, or contents therein, e.g., laundry detergent, dish washing detergent, or any other product which utilizes one of more anionic surfactants. Such compositions would be beneficial for use by consumers who suffer from irritations caused by anionic surfactants, such as allergic reactions, or chemical sensitivity.

[0031] The invention will now be described with respect to the following non-limiting examples:

EXAMPLE 1

[0032] Four dentifrice compositions are prepared with the formulations provided in Table 1 (numbers are expressed in percent weight). Compositions A1, A2 and Z1, Z2 differ in type of surfactant present (anionic vs. nonionic and zwitterionic respectively). Compositions A1, Z1 and A2, Z2 differ in the amounts and type of flavor present.

Table 1

Ingredient	A1	Z1	A2	Z2
Glycerin	3	3	3	3
Xanthan gum	0.8	0.8	0.8	0.8
Propylene glycol	5	5	5	5
Sorbitol	23.8	19.7	23.8	19.7
Sodium fluoride	1.105	1.105	1.105	1.105
Sodium saccharin	0.35	0.35	0.35	0.35
Sodium benzoate	0.5	0.5	0.5	0.5
Potassium sorbate	0.1	0.1	0.1	0.1
Cetylpyridinium chloride		0.1		0.1
Dibasic potassium phosphate	2	2	2	2
Sodium hydroxide			0..3	0.3
Polyoxyl 40 hydrogenated castor oil	3	3	3	3
Zeodent 165	3	3	3	3
Zeodent 114	8	8	8	8
Cocoamidopropyl betaine		0.45		0.45
Poloxamer 407		2		2
Sodium methyl cocoyl taurate	1.2		1.2	
Flavor	1	1	4.4	5.4
FD&C Blue #1	trace	trace	trace	trace
Water	QS 100	QS 100	QS 100	QS 100

EXAMPLE 2

[0033] The compositions prepared in Table 1 are provided to an evaluation group, and the group is asked to evaluate the compositions based on foaming characteristics on a scale of 1(low) to 5 (high). The groups are asked to rank the compositions based on quantity and quality of the foam produced. The percentage of users assigning the top two scores (4 and 5) is determined as a "top 2 box" rating, and assigning the bottom two scores (1and 2) is determined as a "bottom 2 box". The top2 boxes are presented in Tables 2 and 3.

Table 2 – Quantity – Foam evaluation

Composition	
A1	58.8%[a]
Z1	46.5%[a]
A2	61.3%[b]
Z2	52.3%[b]

a – Comparison of quantity of foam produced between A1 and Z1 are not statistically significant

b – Comparison of quantity of foam produced between A2 and Z2 are not statistically different

Table 3 – Quality – Foam evaluation

Composition	
A1	58.8%[c]
Z1	46.5%[c]
A2	57.7%[d]
Z2	44.1%[d]

c – Comparison of quality of foam between A1 and Z1 are not statistically different

d – Comparison of quality of foam between A2 and Z2 are not statistically different.

[0034] Surprisingly, the results indicate that the quantity of foam produced in compositions containing nonionic and zwitterionic surfactants (and free of anionic surfactants) is equivalent to the quantity of foam produced in compositions containing an anionic surfactant. Surprisingly, the results also indicate that the quality of foam produced in compositions containing nonionic and zwitterionic surfactants is equivalent to the quantity of foam produced in compositions containing an anionic surfactant.

[0035] It will be appreciated by those skilled in the art that changes and alterations may be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications within the spirit and scope of the present invention as defined by the appended claims.

Claims:

1. A foaming agent for a dentifrice composition, wherein the composition is free of anionic surfactants, the foaming agent comprising a non-ionic surfactant and a zwitterionic surfactant, wherein the foaming agent is free of anionic surfactants, the non-ionic surfactant is a poly(oxyethylene)-poly(oxypropylene) copolymer and the zwitterionic surfactant is an amido betaine and further comprising one antibacterial agent selected from a halogenated diphenyl ether and cetylpyridinium chloride.

2. The agent of claim 1 comprising from 0.1% to 20% of the non-ionic surfactant.

3. The agent of claim 1 or claim 2 wherein the zwitterionic surfactant is selected from the group consisting of cocoamidoethyl betaine, cocoamidopropyl betaine, lauramidopropyl betaine, or combinations thereof.

4. The agent of any one of the preceding claims comprising from 0.1% to 10% of the zwitterionic surfactant.

5. A dentifrice composition comprising the foaming agent of any one of the preceding claims, wherein anionic surfactants have not been added to the composition.

6. The composition of claim 5 further comprising a fluoride ion source in an amount sufficient to provide from 250 ppm to 25,000 ppm fluoride ions.

7. The composition of claim 5 or claim 6 further comprising an effective amount of a desensitizing agent.

8. The composition of claim 7 wherein the desensitizing agent is selected from the group consisting of potassium salts, capsaicin, eugenol, strontium salts, zinc salts, chloride salts, or combinations thereof.

9. The composition of claim 7 wherein the desensitizing agent is selected from the group consisting of potassium nitrate, potassium bicarbonate, potassium chloride, potassium citrate, potassium oxalate, or combinations thereof.

10. The composition of any one of claims 5 to 9 further comprising silica, a humectant, a stabilizing agent, an antibacterial agent, a sweetener, a surfactant, or combinations thereof.

11. The composition of any one of claims 5 to 10 which is a toothpaste.

12. A dentifrice composition comprising a foaming agent comprising:
0.5% of cocoamidopropyl betaine, and
2% of a poly(oxyethylene)-poly(oxypropylene) copolymer,
said dentifrice composition being free of anionic surfactants.

13. The composition of claim 12 further comprising a fluoride ion source, an antibacterial agent, and/or a desensitizing agent.

14. Use of the composition of any one of claims 5 to 13 in the manufacture of a medicament for treating and/or alleviating xerostomia.

15. The use of claim 14 wherein the composition is to be applied to the oral cavity by brushing of the teeth.