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(54) Title: CLEANSING COMPOSITION

(57) Abstract: The present invention relates to a cleansing composition comprising an anti-microbial agent and a sulphur binding and/or oxidising agent, and wherein the pH of the composition is 7 or lower, to a method for preparing the cleansing composition and its use.

CLEANSING COMPOSITION

The present invention relates to a cleansing composition comprising an anti-microbial agent, a first sulphur binding and/or oxidising agent, and optionally a second sulphur binding and/or oxidising agent, and wherein the pH of the composition is 7 or lower, to a method for preparing the cleansing composition and its use.

At the present various cleaning compositions are used in dental care. They are for example used for cleaning dental braces or prostheses, such as artificial teeth. Another use of these cleansing compositions is their use as an oral rinse composition for the treatment of halitose, i.e. breath malodour or for the treatment of periodontitis.

In the mouth and on dental braces and prostheses food residues and cellular debris accumulate. Due to the breakdown of these residues by oral micro-organisms, in particular due to the breakdown of sulphur containing amino-acids, volatile sulphur compounds are formed. These volatile sulphur compounds cause a bad breath or smell of the braces or prostheses. Moreover, the accumulation of cellular debris and food residues provide an excellent environment for growth of oral micro-organisms such as for example *P. gingivalis*, *Peptostreptococcus spp* and *P. intermedia*. These micro-organisms do not only cause malodour but also cause periodontitis and pathological periodontal pockets causing considerable discomfort for patients.

In the art several solutions have been proposed to overcome periodontitis, bad breath or smell of the braces or prostheses. One of the generally applied methods is to use rinse compositions for rinsing the mouth or the braces. These rinse compositions oxidise the volatile sulphur compounds such that no bad smell develops. Other rinse compositions

have an anti-microbial effect on the micro-organisms present in the mouth, which organisms are responsible for causing periodontitis or for break down of the amino acids. This way periodontitis, malodour of the mouth or the braces or 5 prostheses is partially avoided.

Compositions presently used for overcoming periodontitis, a bad breath or smell of braces or prostheses comprise for example chlorohexidine. The effect of chlorohexidine is obtained through its anti-bacterial effect, i.e. its anti-10 bacterial effect on mainly gram negative bacteria. However, chlorohexidine has several disadvantages. One of the most important disadvantages is that if a patient rinses his mouth with chlorohexidine compositions regularly, his teeth and tongue obtain a brownish colour. This is off course a major 15 disadvantage. Another disadvantage of chlorohexidine is that it has no significant anti-bacterial effect on gram positive bacteria at relatively low concentrations. This means that gram positive bacteria will not be effected by the rinse composition and may thus still cause periodontitis or produce 20 the volatile sulphur compounds that cause the malodour.

Other compositions presently used for treating halitose or for the cleaning of braces or prostheses comprise chlorite. The effectiveness of these compositions is obtained when chlorite contacts acids produced by oral bacteria which 25 trigger the formation of chlorine dioxide whereby the odour causing volatile sulphur compounds are destroyed, i.e. oxidized. These compositions are thus only used for breakdown, i.e. oxidation of odour causing compounds, instead of reducing the amount of oral micro-organisms.

30 For example U.S. 5,772,986 describes a kit comprising a first acidic composition for creating an acidic environment in the mouth and a second composition comprising chlorite. Due to the pre-acidification of the mouth with the first

composition the efficacy of the second composition comprising chlorite increases. However the disadvantage of this composition is that a kit has to be used which comprises two compositions, one for acidification and one for breakdown of 5 the sulfur chlorite compounds. Moreover, by using chlorite, only breakdown of the odour causing compounds is obtained without a considerable reduction of oral micro-organisms.

An object of the present invention is to overcome the problems associated with the cleansing compositions presently 10 used.

A first aspect of the present invention relates to cleansing composition comprising an anti-microbial agent, a first sulphur binding and/or oxidising agent, and optionally a second or further sulphur binding and/or oxidising agent, 15 and wherein the pH of the composition is 7 or lower.

An advantage of the present invention is that one composition can be used for both anti-microbial and chemical control of malodour. A further advantage is that the present composition is active against a broad variety of micro 20 organisms such as gram negative and gram positive bacteria, yeast and fungi. Another advantage of the present invention is that only one composition has to be used instead of a kit comprising a first and a second composition such as described in US 5,772,986. Further, by using the composition according 25 to the invention slime and food residues present in the mouth or on dental braces or prostheses can be removed causing inactivation of the micro-organisms present therein.

Moreover, calcium deposits present on the teeth or on the dental braces or prostheses can be removed by using the 30 composition according to the invention.

Another important advantage of the present invention is that the dental braces or prostheses that are treated with the composition according to the invention are substantially

free from oral micro-organisms. Generally dental braces and prostheses are made of porous materials providing a suitable environment for micro-organisms. However due to the treatment with the composition according to the invention micro-
5 organisms and food residues in the porous matrix of the dental braces and/or prostheses are removed. Particularly when patients have previously been treated for periodontitis it is advantageous if the braces and/or prostheses are substantially free of micro-organisms, such that re-
10 contamination of the cleaned places is avoided. It is further noted that the present cleansing composition is preferably an aqueous composition. However, the composition may also be formulated as a dispersion, gel or paste (for example as toothpaste). However, a gel is preferred if the composition
15 is used for cleaning of pathological periodontal pockets.

In an embodiment of the present invention the pH is in the range of 1 to 5, preferably 2-4. This pH range is advantageous for reasons that it creates an environment wherein micro-organisms may effectively be killed.

20 Furthermore, a relatively low pH has a calcium binding effect. This effect is especially advantageous in the present invention for reasons that calcium accumulation may have taken place on the teeth or on the brace or prostheses resulting in a poor appearance thereof. Another advantage of
25 the above mentioned pH range is that the slime layer formed by food residues and cellular debris present in the oral pharynx is at least partly destroyed. This destruction of the slime layer makes it possible that anaerobe bacteria, that cause periodontitis or a malodour, present under or in
30 the slime layer can effectively be inactivated by the antimicrobial agent present in the composition. Moreover, due to the relatively low pH, proteins present in the mouth or on

the dental braces or prostheses denaturate such that they can easily be removed.

The amount of the first sulphur binding and/or oxidising agent and/or second sulphur binding agent is between 0,005 and 1 wt%, preferably between 0,04 and 1 wt%, more preferably between 0,04 wt% and 0,3 wt%, most preferably between 0,1 and 0,3 wt%. Within these ranges the sulphur compounds formed by the bacteria are substantially removed, causing the malodour to disappear.

Particular preferred as the first sulphur binding/oxidising agent is ammonium. Ammonium is preferred because it is very reactive with sulphur compounds, thus taking away the malodour. Furthermore, ammonium also helps to dissolve fat-residues present in the mouth. This means that sulphur compounds contained in these fat residues (such as food debris) can be taken away. Furthermore, since the fat residues dissolve, the efficacy of the anti-microbial agent used in the present composition is increased. After all, the anaerobe bacteria contained in the fat residues are brought into contact with the anti-microbial agents more easily. The use of ammonium thus increases the efficacy of the cleansing composition.

It is even more preferred if the amount of ammonium in the composition is between 0,04 and 0,5 wt%, preferably between 0,1 and 0,5 wt%. Within this range the efficacy increases even more.

It is further preferred if the second sulphur binding/oxidising agent comprises calcium, sodium, sodium benzoate, a benzene-derivate, an aromatic hydrocarbon, acetyl salicyclic acid or mixtures thereof. It may however also be possible that one or more of these sulphur binding/oxidising agents form the first sulphur binding/oxidising agent. By using one or more of these sulphur binding/oxidising agents

reduction of the sulphur compounds present in the mouth, pharynx or on prostheses improves even further.

In a preferred embodiment the anti-microbial agent is an organic acid. The anti-microbial agent is more preferably a 5 hydroxy acid, citric acid, acetic acid, acetyl salicylic acid, butyric acid, lactic acid, tartaric acid, and/or NaHCO₂. By using one of these anti-microbial agents the micro-organisms producing the sulphur compounds, i.e. causing the malodour, are substantially inactivated. This means that 10 no substantial formation of a malodour will occur.

The amount of organic acid or acids in the composition preferably ranges from 1,0 to 50 wt%, preferably from 30 to 45 wt% or from 1 to 10 wt%. Within these ranges a particular good efficacy of the composition is obtained.

15 It is even more preferred if the amount of acetic acid in the composition ranges from 0,05 to 10 wt%, preferably from 1 to 10 wt%, more preferably from 1 to 6 wt%. Besides its efficacy as an anti-microbial agent it also dissolves fat. This means that fat residues from for example food residues 20 are (partly) dissolved and that the sulphur binding/oxidising agents can easily bind or react with these compounds. Also the inactivation of micro-organisms present in the mouth, pharynx or on prostheses or instruments is improved.

Further, preferably tartaric acid is used as an organic 25 acid. Tartaric acid provides an improved efficacy. Preferably the amount of tartaric acid ranges between 0,5 and 10 wt%, preferably between 0,5 and 3 wt%.

In a preferred embodiment according to the present invention the amount of the first sulphur binding/oxidising 30 agent is between 0,1 and 0,8 preferably between 0,1 and 0,3 wt% of the composition, the amount of anti-microbial agent is between 30 to 45 wt% of the composition and the pH is between 2 and 4. Such an embodiment is particular suitable for use as

a cleansing composition for cleaning prostheses, such as dental prostheses and braces, dental instruments such as surgical instruments and stainless steel dental and surgical instruments. Preferably, the first sulphur binding/oxidising agent is ammonium and the anti-microbial agent tartaric acid and/or acetic acid.

In another preferred embodiment the amount of the first sulphur binding/oxidising agent is between 0,03 and 0,15 wt% of the composition, the amount of anti-microbial agent is 10 between 1 and 8 wt% of the composition and the pH is between 2 and 4. This embodiment is particularly suitable for use in the prophylaxes or treatment of disorders of the naso and/or oro pharynx, such as halitosis, periodontitis, gingivitis and/or the treatment of human skin or vaginosis. Preferably, 15 the first sulphur binding/oxidising agent is ammonium and the anti-microbial agent tartaric acid and/or acetic acid.

The anti-microbial agent and the sulphur binding agent are preferably the same. This is advantageous for reasons that only one agent has to be used resulting in lower 20 production and raw material costs. A preferred agent having both anti-microbial and sulphur binding properties is acetyl salicylic acid.

In a preferred embodiment of the present invention the amount of salicylic acid and/or NHCO₃ 0,1 and 2,5 wt%. 25 Salicylic acid is preferred for reasons that it has both anti-microbial properties and sulphur binding (oxidising) properties. Moreover, it has a anaesthetic effect. NHCO₃ is preferred for reasons that it also improves the shelf-life of the composition.

30 In a specially preferred embodiment of the present invention the composition comprises a fluoride source. The addition of a fluoride source makes the cleansing composition particularly suitable for treatments in the mouth,

particularly for use in the treatment of halitose, pathological periodontal pockets and/or periodontitis in the mouth. By using the fluoride source a possible demineralization of the teeth by the acidic composition is 5 substantially avoided, whilst obtaining a reduction of oral micro-organisms and a break down of volatile sulphur compounds present in the mouth.

The fluoride source is preferably NH₂F, sodium fluoride, calcium fluoride, potassium fluoride, lithium fluoride, 10 aluminium fluoride, zinc fluoride, zirconium fluoride, sodium monofluorophosphate, acidulated phosphate, fluoride, stannous chloro fluoride, magnesium fluoride, potassium trifluorostannous, titanium fluoride, iron fluoride, stannous hexafluorozirconate.

15 The composition preferably comprises between 0,05 and 0,5 wt% NH₂F and/or NaF, preferably between 0,1 and 0,2 wt%, more preferably about 0,15 wt%.

20 Preferably the composition comprises enzymes such as lysozyme and/or lactoperoxidase. An advantage of the use of these enzymes is that an increased and faster anti-microbial effect is obtained when using the composition.

In order to make the composition more attractive colourings, flavourings and/or stabilisers may be added to the composition.

25 A second aspect of the present invention relates to a method for preparing the above mentioned composition, comprising the steps of: preparing a mixture of an anti-microbial agent, a first sulphur binding and/or oxidising agent, and optionally a second sulphur binding and/or 30 oxidising agent, and adjusting the pH of the mixture to 7 or lower.

A third aspect of the present invention relates to a cleansing composition obtainable by the above mentioned method.

5 A fourth aspect of the present invention relates to the above mentioned composition for use as a medicament.

A fifth aspect of the present invention relates to the use of the above mentioned composition for the manufacture of a medicament for the treatment or prophylaxis of disorders of the naso and/or oro pharynx, such as halitose, 10 periodontitis, gingivitis, cleansing of root (endodontic) canals and/or the treatment of human skin or vaginosis.

A sixth aspect of the present invention relates to the use of the above mentioned cleansing composition for cleansing prostheses, such as dental prostheses and braces, 15 dental instruments, such as surgical instruments and stainless steel dental and surgical instruments.

Reference will now be made to the following examples intended to illustrate preferred embodiments of the invention but which are not to be construed as limiting the scope of 20 this invention.

Examples

Example 1 Denture cleansing composition

25 An aqueous cleansing composition was prepared comprising 500 ml acetic acid (25%/l) as a calcium binding agent, 200 ml ammonia (10%/l NH₃) which in reaction becomes NH₄⁺ which is a sulphur binding agent, 100 ml acethyl salicyclic acid (5%/l), 30 and about 200ml citric acid (5-10%/l) to lower the pH to 2. The composition further comprised a menthol flavouring for giving the composition a pleasant odour. Three used braces and two prostheses were immersed in the composition during

about fifteen minutes. After the treatment no calculus, no debris and no malodour remained.

Example 2 Denture cleansing composition

5

An aqueous cleansing composition was prepared by preparing a mixture comprising about 0,15 wt% salicyclic acid, comprising about 2,5 wt% tartaric acid, about 6 wt% acetic acid, about 35 wt% citric acid and about 55 wt% water.

10 The mixture also contained about 0,2 wt% ammonium obtained through the addition of ammonia to the aqueous mixture. For improving the taste and the smell of the mixture peppermint oil and sodium cyclamate was used. The composition obtained was particularly suitable for the cleansing of prostheses

15 such as sets of dentures.

The efficacy of the composition was tested by 158 persons all wearing dentures, such as partial dentures, frame prostheses and orthodontic braces. All respondents were asked to use the cleansing composition for cleaning their dentures

20 and to note the time it took before the denture was substantially clean, i.e. until all food residues were substantially removed and the dentures did no longer have a malodour. As is clear from table 1, all respondents indicated that within 25 minutes their dentures were substantially

25 clean and more than 50% of the respondents even indicated that their dentures were already clean after 15 minutes.

Table 1

Time before denture is perceived as clean (min.)	Number of respondents
5	
10	15
15	73
20	43
25	27

10 As is clear from table 1 the cleansing composition according to the present invention had a relatively high efficacy.

Example 3 Instrument cleansing composition

15 In the same way as in example 2 the following composition was prepared for cleaning stainless steel dental instruments. The composition prepared comprises: about 0,5 wt% ammonium, about 0,15 wt% salicyclic acid, about 7,5 wt% tartaric acid, about 8,0 wt% acetic acid, about 27,5 wt% citric acid

20 (monohydrate), about 1,5 wt% sodium cyclamate and about 55 wt% water. This composition was tested on 10 dental instruments (5 gingivectomy-knives; 5 dental-mirrors). All instruments were substantially clean within 15 minutes.

25 **Example 4 Oral cleansing composition**

An aqueous cleansing composition was prepared comprising about 25mg per litre NH₂F as a fluoride source, 100 ml ammonia (8%/l), 100ml acethylsalicyl acid (5%/l), 400 ml acetic acid (20 %/l), NaHCO₃ (4%/l) with Na as a second sulphur binding agent and CO₃ for oxidation, and about 500ml citric acid (10- 20 %/l) to lower the pH to 3. Further, a menthol

flavouring to give the composition a pleasant taste and sorbitol to sweeten the composition was added. Six patients suffering from halitosis rinsed their mouth twice a day during two minutes. After two weeks none of the patients 5 suffered from halitosis.

Example 5 Oral cleansing composition

An aqueous cleansing composition was prepared comprising 10 about 0,15 wt% salicyclic acid, about 0,15 wt% NaF, about 0,5 wt% NHCO₃, about 1,0 wt% lactic acid, about 1,0 wt% tartaric acid, about 1,2 wt% acetic acid, about 1,5 wt% citric acid, about 28 wt% sorbitol, about 0,1 wt% ammonium. This composition was tested among six patients suffering from 15 halitosis and they were asked to rinse their mouth twice a day during two minutes. After two weeks none of the patients suffered from halitosis.

Example 6 Periodontitis composition (gel)

An aqueous cleansing composition was prepared comprising 20 about 25 mg per litre NH₂F as a fluoride source, 200 ml ammonia (12%/l), 100 ml acethylsalicyl acid (5%/l), 400 ml acetic acid (20%/l), 100 ml NaHCO₃ (4%/l), and 200 ml citric acid (10-20%/l) to lower the pH to pH 3. Also human enzymes 25 were added to the composition, such as lysozym and/or lactoperoxidase, or similar. Further, a menthol flavouring was added for improving the taste and sorbitol was added as a sweetener. Six patients rinsed their mouth twice a day during 30 two minutes for three weeks. During this period they were treated for periodontitis with scaling and root planning of the pathological periodontal pockets and these pockets were irrigated with the same composition. This composition in a

gel form was applied into the pathological pockets with a syringe for even greater effectiveness. After the treatment none of the patients suffered from periodontitis after six months.

5

Example 7 Periodontitis composition (solution)

An aqueous cleansing composition was prepared comprising about 0,1 wt% ammonium, about 0,15 wt% salicyclic acid, about 10 0,15 wt% NaF, about 0,75 wt% NaHCO₃, about 1,35 wt% lactic acid, about 1,5 wt% tartaric acid, about 1,2 wt% acetic acid, about 2,5 wt% citric acid, about 28 wt% sorbitol and about 64 wt% water. Six patients rinsed their mouth twice a day during two minutes for three weeks. During this period they were 15 treated for periodontitis with scaling and root planning of the pathological periodontal pockets and these pockets were irrigated with the same composition. This composition as an aqueous solution was applied into the pathological pockets with a syringe for even greater effectiveness. After the 20 treatment none of the patients suffered from periodontitis after six months.

For the same reasons that the above mentioned solution is active against most micro organisms in the mouth, Gingivitis can be treated by rinsing the mouth during two minutes twice 25 a day during fourteen days. In heavy cases of illness cotton cloths soaked in the rinse can be applied directly around the teeth in contact with the gingiva.

Considering the similarity between oral and vaginal mucous tissues this therapy, i.e. applying a composition 30 according to the present invention, will also be effective against micro organisms in the vagina (vaginose).

1. Cleansing composition comprising an anti-microbial agent, a first sulphur binding and/or oxidising agent, and a second or further sulphur binding and/or oxidising agent, wherein the pH of the composition is 7 or lower, wherein the anti-microbial agent is a hydroxyl acid, citric acid, acetyl salicyclic acid, butyric acid, lactic acid, tartaric acid, acetic acid, malic acid or mixtures of any of these acids, wherein the first sulphur binding/oxidising agent is ammonium in an amount between 0.04 and 0.5 wt% of the composition and wherein the second or further sulphur binding and/or oxidising agent is NaHCO₃ or is a combination of NaHCO₃ with salicyclic acid.

15 2. Cleansing composition according to claim 1, wherein the pH of the composition is between 2 and 4.

20 3. Cleansing composition according to claim 1 or 2, wherein the anti-microbial agent is an organic acid, wherein the amount of organic acid preferably ranges from 1,0 to 50 wt%.

25 4. Cleansing composition according to any of claims 1-3, wherein the anti-microbial agent is present in an amount ranging from 0,05 to 10 wt% of the composition.

30 5. Cleansing composition according to any of claims 1-4, wherein the amount of tartaric acid ranges between 0.5 and 10 wt%.

6. Cleansing composition according to any of claims 1-5, wherein the composition comprises a fluoride source selected from the group consisting of NH_2F , sodium fluoride, calcium fluoride, postassium fluoride, lithium fluoride, 5 aluminium fluoride, zinc fluoride, zirconium fluoride, sodium monofluoro-phosphate, acidulated phosphate, fluoride, stannous chloro fluoride, magnesium fluoride, potassium trifluorostannous, titanium fluoride, iron fluoride, stannous hexafluoro-zirconate.

10

7. Cleansing composition according to claim 6, wherein the composition comprises between 0,05 and 0,5 wt% NH_2F and/or NaF .

15

8. Cleansing composition according to any of claims 1-7, wherein the composition comprises enzymes.

20

9. Cleansing composition according to any of claims 1-8, wherein the composition comprises colourings, flavourings and/or stabilisers.

25

10. Method for preparing a composition according to any of claims 1-9, comprising the steps of: preparing a mixture of an anti-microbial agent as defined in any of the claims 1-9, a first sulphur binding and/or oxidising agent as defined in any of claims 1-9, and a second or further sulphur binding and/or oxidising agent as defined in any of claims 1-9, and adjusting the pH to a value as defined in any of claims 1-9.

30

11. Method according to claim 10, wherein a fluoride source as defined in any of claims 1-9 is added to the mixture.

12. Method according to claim 10 or claim 11, wherein to the mixture enzymes, colourings, flavourings and/or stabilisers are added.

5

13. Cleansing composition according to any of claims 1-9 for use as a medicament.

14. Use of a composition according to any of claims 10 1-9 for the manufacture of a medicament for the treatment or prophylaxis of disorders of the naso and/or oro pharynx, such as halitosis, periodontitis, and/or the treatment of human skin or vaginosis.

15 15. Use of a composition according to any of claims 1-9 for the manufacture of a medicament for the treatment or prophylaxis of gingivitis.

16. Use of the cleansing composition according to 20 any of claims 1-9 for cleaning prostheses, dental instruments and/or stainless steel dental and surgical instruments.

17. A method of treatment or prophylaxis of a 25 disorder of the naso and/or oro pharynx and/or skin or vaginosis, including the step of administering to a human the composition according to any of claims 1-9 to thereby therapeutically or prophylactically treat said disorder.

30 18. The method of claim 17, wherein the disorder is halitosis, periodontitis or gingivitis.

19. A method of cleaning a prothesis or dental instrument including the step of contacting the prothesis or dental instrument with the cleaning composition according to any of claims 1-9 to thereby clean the prothesis or dental
5 instrument.

20. The method of claim 19, wherein the prothesis is a dental prothesis or brace and/or the dental instrument is a surgical instrument inclusive of stainless steel dental
10 and surgical instruments.