Chlorhexidine has however the major drawback of causing brownish staining on the surface of the teeth as well as on prosthesis and tongue, which reduce significantly the patient compliance.

In order to overcome said problem, anti-discloroRant systems (ADS) have been developed, which comprise adding in the chlorhexidine formulation sodium metabisulphite, for its property of preventing the Maillard reaction, and ascorbic acid, which interfere with the formation of ferric disulfur organic compound.

Though the above, there is the need of improved mouthwash preparations, which could solve the problem of the teeth discoloration.

Summary of the invention

It has been surprising found that a combination of a metabisulfite salt of an alkali or an alkaline-earth metal thereof, ascorbic acid or an alkali or an alkaline-earth metal salt thereof, hyaluronic acid or a salt thereof and polyvinylpyrrolidone-vinylacetate can be used as an improved anti-pigmentation system in a mouthwash preparation based on chlorhexidine.

Brief description of the figures

Fig. 1 shows the results of the test on the composition of the invention.

In ad additional aspect, it is disclosed the use of the mouthwash of the invention for the protection of gingiva and oral mucosa and for the prevention and treatment of gingivitis.

Detailed description of the invention

According to a first object of the invention, it is disclosed an anti-pigmentation system that can be used for preparing chlorhexidine based mouthwashes.

In particular, according to the present invention, the mouthwash comprises an amount of chlorhexidine of from about 0.01% to 0.3% (w/w) and preferably of from about 0.09% to 0.25% (w/w).

According to an even preferred embodiment, chlorhexidine is comprised in a quantity of about 0.2% (w/w).

Chlorhexidine may be present as such or in the form of a salt or a complex thereof.

A salt may be represented by chlorhexidine digluconate.

As per the anti-pigmentation system of the invention, it is represented by a composition comprising: a metabisulfite salt of an alkali or an alkaline-earth metal, ascorbic acid or an alkali or an alkaline-earth metal salt thereof, hyaluronic acid or a salt thereof and polyvinylpyrrolidone-vinylacetate.

As per the polyvinylpyrrolidone-vinylacetate, according to the present invention, it can be comprised in an amount of about 0.02% to about 0.5% (w/total weight of the mouthwash).

Preferably, the polyvinylpyrrolidone-vinylacetate may be comprised in an amount of about 0.02% to about 0.5%, preferably of about 0.15% to about 0.2% and more preferably it is comprised in an amount of about 0.09% to about 0.12% (w/total weight of the mouthwash).

As above indicated, the mouthwash comprising the anti-pigmentation system disclosed represents a further object of the invention.

According to another aspect, it is disclosed a process for the preparation of a mouthwash based on chlorhexidine and comprising the anti-pigmentation system of the invention.

In an additional object, it is disclosed a method for the prevention and treatment of plaque comprising the use of the mouthwash of the invention.

In a preferred aspect, it is disclosed a method for the cosmetic prevention and treatment of plaque comprising the use of the mouthwash of the invention.

In an additional object, it is disclosed a method for the prevention of stains on the surface of the

and treatment of plaque and/or of gengivitis, in the prevention of the bacteria growth, as an anti-bacterial.

According to a further embodiment, the mouthwash of the invention can be used in the treatment of parodontitis when used once or twice a day for at least one minute and a period of from 7 to 15 days at the concentration of 0.2% followed by the use once or twice a day for at least one minute for about 21 days at the concentration of 0.12%.

According to an additional object of the invention, it is disclosed the use of polyvinylpyrrolidone-vinylacetate combined with chlorhexidine in a mouthwash for the treatment of or the prevention of the formation of plaque.

EXAMPLE 1

According to the above description, the following mouthwash preparation can be:

COMPONENT	**QUANTITY**
water	q.b. to 100%
sugar	6-10%
humectants	0.1-0.2%
surfactants	1.0-3%

to a mouthwash comprising an anti-pigmentation system that does not include hyaluronic acid.

When polyvinylpyrrolidone-vinylacetate is also included in the anti-pigmentation system of the invention, it has been observed a synergic action with chlorhexidine against bacteria and against the formation of the bacterial biofilm.

In addition to that, polyvinylpyrrolidone-vinylacetate has also been seen as acting in synergy with hyaluronic acid in the formation of a mechanical barrier, which can protect both the teeth surface and the soft tissues (gingiva and oral mucosa).

Polyvinylpyrrolidone-vinylacetate (PVP-VA) is a safe ingredient: no adverse reactions after intake are known at present, PVP VA is widely used on industrial scale in cosmetics, food preparations and medications. The value of the acceptable daily dose is high (i.e., 50 mg/kg), and is far above the values established for food and pharmacological products. In addition, the component is highly soluble in water.

Surprisingly, the above advantageous effects have been noticed to be not be to the detriment of the anti-bacterial effect.

Those skilled in the art will be able to make modifications or adaptations to the present invention,

CLAIMS

1. An anti-pigmentation system for a chlorhexidine based mouthwash, comprising a metabisulfite salt of an alkali or an alkaline-earth metal, ascorbic acid or an alkali or an alkaline-earth metal salt, hyaluronic acid or a salt thereof and polyvinylpyrrolidone-vinylacetate.

2. A mouthwash comprising chlorhexidine in a quantity of about 0.01% to 0.3% (w/w) and preferably of about 0.09% to about 0.25% (w/w) comprising the anti-pigmentation system according to the preceding claim.

3. The mouthwash according to the preceding claim, wherein chlorhexidine is comprised in a quantity of about 0.2% (w/w).

4. The mouthwash according to the preceding claim 2 or 3, wherein chlorhexidine is in the form of a salt or a complex thereof.

5. The mouthwash according to the preceding claim 2, 3 or 4, wherein chlorhexidine is in the form of chlorhexidine digluconate.

6. The mouthwash according to any one of the preceding claims 2 to 5, wherein the metabisulfite salt is comprised in an amount of about 0.1% to about

about 0.8% to about 2.0% and preferably of about 1% to about 1.5% (w/total volume of the mouthwash).

12. The mouthwash according to any one of the preceding claims 2 to 11, wherein the hyaluronic acid salt thereof can be present in the form of sodium or potassium salt or a mixture of the two salts.

13. The mouthwash according to any one of the preceding claims 2 to 12, wherein hyaluronic acid or a salt thereof is comprised in an amount of about 0.01% to about 1.5% and preferably of about 0.05% to about 1.2% (w/total volume of the mouthwash).

14. The mouthwash according to any one of the preceding claims 2 to 13, wherein polyvinylpyrrolidone-vinylacetate is comprised in an amount of about 0.02% to about 0.5% (w/total weight of the mouthwash), preferably in an amount of about 0.15% to about 0.2% and more preferably of about 0.09% to about 0.12% (w/total volume of the mouthwash).

15. The mouthwash according to any one of the preceding claims 2 to 14, further comprising one of more of the following additives: sweeteners and/or flavorings, a source of fluorine, humectant, preservatives, surfactants, pH regulators, coloring agents.

present in an amount of about 0.1% to about 0.2% (w/total volume of the mouthwash).

22. The mouthwash according to any one of the preceding claims 16 to 21 wherein the preservatives selected in the group comprising the benzoates, phenossietanolo, chlorphenesin.

23. The mouthwash according to any one of the preceding claims 16 to 22, wherein the surfactant is present in an amount of about 0.1% to about 0.2% (w/total volume of the mouthwash).

24. The mouthwash according to any one of the preceding claims 16 to 24, wherein the surfactant is selected in the group comprising hydrogenated castor oil PEG40, Poloxamer 407 or other suitable surfactants.

25. The mouthwash according to any one of the preceding claims 16 to 24, wherein the pH regulators is selected in the group comprising citric acid and its salts, like sodium salt.

26. The mouthwash according to any one of the preceding claims 16 to 25, wherein the coloring agent is selected in the group comprising CI 1940, CIU 42090, CI 17200 and other suitable coloring agents.

27. The mouthwash according to any one of claims 2 to 26, for use in the therapeutic prevention and treatment of plaque.

28. The mouthwash according to any one of claims 2 to 26, for use in the therapeutic prevention and treatment of gingivitis.

29. The mouthwash according to any one of claims 2 to 26, for use in the prevention of stains on the surface of the teeth.

30. The mouthwash according to any one of claims 2 to 26, for use in the protection and treatment of gingiva.

31. Use of chlorhexidine in a quantity of about 0.01% to 0.3% (w/w) and preferably of about 0.09% to about 0.25% (w/w); and an anti-pigmentation system for a chlorhexidine based mouthwash, comprising a metabisulfite salt of an alkali or an alkaline-earth metal, ascorbic acid or an alkali or an alkaline-earth metal salt, hyaluronic acid or a salt thereof and polyvinylpyrrolidone-vinylacetate; in the manufacture of a medicament in the form of a mouthwash according to any one of claims 2 to 26 for the prevention and treatment of:

a) plaque;

b) stains on the surface of teeth; and

c)gingivitis.

32. Use of chlorhexidine in a quantity of about 0.01% to 0.3% (w/w) and preferably of about 0.09% to about 0.25% (w/w); and an anti-pigmentation system for a chlorhexidine based mouthwash, comprising a metabisulfite salt of an alkali or an alkaline-earth metal, ascorbic acid or an alkali or an alkaline-earth metal salt, hyaluronic acid or a salt thereof and polyvinylpyrrolidone-vinylacetate; in the manufacture of a medicament in the form of a mouthwash according to any one of claims 2 to 26 for the protection of gingiva and oral mucosa.