A two component preparation useful for preparing a mouth rinse includes (a) a first dry component of calcium chloride hexahydrate and a stabilizer and (b) a second dry component of phosphate and a stabilizer, and optionally fluoride. The two component preparation, upon dissolution of said dry components (a) and (b) in a predetermined amount of water, yields a supersaturated solution of calcium and phosphate ions.
Two component mouth rinse preparation

The present application relates to a two component preparation useful for preparing a mouth rinse, comprising (a) a first dry component comprising calcium chloride hexahydrate and stabilizing agent and (b) a second dry component comprising phosphate and a stabilizing agent, and optionally fluoride. In particular, the inventions relates to a dry, two component preparation, which upon dissolution in water yield a supersaturated solution of calcium and phosphate ions.

Background of the invention

It is known that the use of various medications and different treatment regimes exert side effects resulting in severe injury on the mucous membrane of the oral cavity as well as severe dental injuries. Also, disorders such as AIDS and cancer treatment regimes may result in reduced activity of the immune system which again may result in severe conditions of the oral cavity, such as e.g. mucositis and severe infections.

Cancer patients undergoing bone marrow transplantation are typically administered immune depressing medicinal agent to depress the immune system and thus avoid rejection of the transplanted tissue or cells. Furthermore, cancer patient undergoing cytotoxic drug treatment may often also have reduced immune system due to the cytotoxic effect on the leucocytes. A patient having a depressed immune system is also susceptible to infection resulting in prophylactic treatment with antibiotics. Repetitive and large use of antibiotics, as well as head and neck radiation, may again result in severe dental caries.

Also other patients having reduced immune system activity or being dependent on continuous treatment with antibiotics or other medications, such as e.g. AIDS patients, may be affected with the same severe side effects on both hard and soft tissue of the oral cavity. Reduced immune system activity also results in an increased risk of systemic infections due to the increased risk of passage pathogens from the oral cavity to the blood stream.

Chemotherapeutic treatment may also result in discouraging eating and malnutrition due to stomatitis, sore throat, change in taste sensation, stomach cramping, nausea, vomiting, diarrhoea etc. The malnutrition condition may further result in undesirable condition affecting both hard and soft tissue in the oral cavity.

Saliva provides a natural antibacterial protection (due to the fact that saliva provides a tissue coating film). Furthermore, the saliva also has a remineralizing potential due to the lubrication of the mucosa. Several medicinal agents, as well as head and neck radiation, result in dryness of the mouth due their adverse effect resulting in reduced salivary production. Mouth dryness as a consequence of adverse effect of medicines may thus lead to various undesired conditions in the
oral cavity. Non-limiting examples of medicinal agent which may result in dry mouth are e.g. the anti prostate agent bicalutamide, antidepressive medicaments (citalopram, fluoxetine, paroxetine), carbamazepine (anti epilepticum), lansoprazol (proton pump inhibitor), klozapine (neurolepticum), topiramate (anticonvulsant), olanzapine (anti schizophrenia) etc.

The salivary production may also be severely reduced upon radiation therapy as radiation causes atrophy of the salivary glands in the oral cavity, cf. Medical News, 1975, JAMA, Vol 234, no. 6, pp. 577 - 578.

An example of another disease affecting the salivary glands leading to reduced salivary production and dry mouth is Sjogren's syndrome. Thus, patients having Sjogren's syndrome are also exposed to developing undesirable conditions of the oral cavity, such as mucositis etc.

Many of the side effects and symptoms described above may be treated or avoided by preventive administration of a supersaturated solution of calcium and phosphate. It is known that the treatment with calcium and phosphate mouth rinse may have beneficial effect by reducing mucositis in patients undergoing stem cell transplantation, c.f. Papas et al. (2003), Bone Marrow Transplantation, 00, 1-8. It is furthermore known that the administration of supersaturated calcium phosphate solution, used twice a day after fluoride treatment results in remineralization, c.f. Medical News, 1975, JAMA, vol. 234, no. 6, pp. 577 - 578.

US 6387352 discloses a mouth wash composition supersaturated with respect to calcium and phosphate, suitable for treating patients having dental caries or other conditions in the oral cavity, e.g. as a result of chemotherapy or radiation therapy. More specifically, US 6387352 discloses a formulation which is effective for use as a dental rinse or mouth wash, wherein said formulation comprises an aqueous calcium component (calcium stock solution); and separated there from, an aqueous phosphate component (phosphate stock solution).

US 5993785 disclose an aqueous solution which are supersaturated with respect to calcium and phosphate(s) and which further comprise a stabilizing agent in an amount sufficient to enable the calcium ions and phosphate ions to remain in supersaturated solution so that it may be used as a dental rinse or mouth wash. US 5993785 likewise teaches an aqueous calcium component, and separated there from, an aqueous phosphate component.

A composition providing a super saturated solution of calcium and phosphate is at the moment marketed as Caphosol™ [http://www.caphosol-us.com/default.asp]. Caphosol™ is used to lubricate the mucosa and maintain the integrity of the oral cavity through its mineralizing potential. It is described for inter alia mucositis and dry mouth. Caphosol™ consist of two stock solutions provided in separate, single dosages ampoule, one comprising calcium ions and the other one comprising
phosphate ions, which upon mixing yield the super saturated mixture. Upon
administration, the calcium component and the phosphate component is mixed by
the patient prior to administration.

Thus, patients undergoing chemotherapy or radiation therapy due to cancer, or
patients having a depressed or ineffective immune system (patients undergoing bone
marrow transplantation, AIDS patients etc), patients having Sjogren's syndrome,
patients with imperfect or non-functioning salivary glands, patients being
administrated medicines resulting in dry mouth, patients with high susceptibility to
dental caries or who aims at an increased oral health, patients with inflammatory
and/or ulcerative lesions in the oral cavity or the susceptibility thereof, etc might
benefit from treatment with a supersaturated calcium and phosphate solution.

The challenge of preparing mouth washes comprising the necessary amounts of
calcium and phosphate ions to provide the beneficial effects of the soft and hard
tissue of the oral cavity, is to prepare a solution of calcium ions and phosphate ions
which to not results in the precipitation of calcium and phosphate complexes
thereof. In US 6387352 and US 5993785, super saturated solutions which do not
precipitate within the time needed to rinse the oral cavity are disclosed as referred
to above. Said super saturated solutions disclosed in US 6387352 and 5993785, as is
the fact with Caphosol™, require the patient to mix together two previously
prepared and packaged aqueous solutions comprising calcium ions and phosphate
ions, respectively. According to one aspect of these prior art mouth rinses two
separate aqueous concentrates are provided that requires dilution by the patient.
According to another aspect of the prior art mouth rinses, the aqueous stock
solutions come pre-diluted and separately packaged.

The prior art mouth rinses discussed above suffer from several disadvantages,
however. One such disadvantage is that the starting components used in
manufacturing Caphosol™ have to be stirred in large vessels for several hours
before they are dissolved properly. Because of this, the preparations disclosed in the
prior art must be delivered to the patient as separately packaged, aqueous solutions,
which must be mixed together by the patient. This greatly increases the
manufacturing, transport, packaging and storage costs of the product. In addition, it
is further well known that the use of aqueous solutions as a formulation form
necessitates sterilization procedures. In contrast to an aqueous formulation, a solid
formulation avoids labour-intensive sterilization or purified water procedures and
most often provides for a longer storage life. In addition, the use of such liquid
products is inconvenient for the patient, for example requiring the patient to carry
large and heavy packaging when traveling.

It is therefore an object of the present invention to provide a mouth rinse having the
same therapeutically effective composition as the prior art product Caphosol™ and
as described in US 6387352 and US 5993785, but which is provided to the patient
in a dry form in which the patient may dissolve the components in water his or her
self.

It is further an object of the present invention to overcome the disadvantages
connected with the stock solution system disclosed in the prior art related to e.g.
transport cost, packaging, sterilization and storage life etc.

Summary of the invention

The present application thus provides a two component preparation useful for
preparing a mouth rinse, comprising (a) a first dry component comprising calcium
chloride hexahydrate and a stabilizer and (b) a second dry component comprising
phosphate and a stabilizer, and optionally fluoride. In particular, the invention
relates to a dry, two component preparation, which upon dissolution of said dry
components (a) and (b) yields a supersaturated solution of calcium and phosphate
ions.

The calcium chloride hexahydrate in component (a) and phosphate in component (b)
are present in amounts sufficient to provide, upon dissolution, a super saturated
solution thereof having the concentrations of calcium and phosphate ions as
described in US 6387352 and US 5993785 (the entire contents of which are hereby
incorporated by reference as if repeated verbatim herein for establishing such
numerical values), said amounts being derivable by known methods of calculation.
A month rinse solution obtained by the dissolution of dry components (a) and (b)
according to the present invention is stable in a sufficient period of time to allow for
the combined solution to be used as a mouth rinse solution.

According to one aspect, the stabilizer contained in dry components (a) and (b) of
the present two component preparation is an alkali metal such as e.g. earth alkali
halides, such as e.g. sodium chloride.

The amount of sodium chloride in the two component preparation according to the
present invention is sufficient to facilitate dissolution of the calcium and phosphate
ions and avoiding precipitation once dry components (a) and (b) are dissolved and
mixed.

The two component preparation may also optionally comprise other physiologically
acceptable excipients such as e.g. flavoring agents, coloring agents, and / or
preservatives well known to the skilled person.

According to another aspect of the present invention, a kit is provided comprising
unit dosages containers comprising a powder mixture comprising calcium chloride
hexahydrate and stabilizer and separated therefrom unit dosages containers
comprising a powder mixture comprising phosphate and a stabilizer, and optionally
fluoride and an instruction manual.
According to another aspect of the invention, the two component preparation is provided in the form of two effervescent tablets, and according to yet another aspect as a single effervescent tablet comprising a first segment of the tablet containing the dry calcium component, a second segment of the tablet containing the dry phosphate component, and a layer of an inert material separating the two segments of the tablet.

The present invention also provides a method for treating or preventing conditions and disorders of the soft and/or hard tissue of the oral cavity, which method comprises the steps:

a) providing a two component preparation of the present invention comprising a) a first dry component comprising calcium chloride hexahydrate and stabilizer and b) a second dry component comprising phosphate and a stabilizer, and optionally fluoride.

b) dissolving, or instructing a patient to dissolve, component a) and component b) in water approximately immediately prior to use,

c) administering the solution obtained in c) to a patient in need thereof.

The patient in need thereof may be any patient suffering of conditions in the oral cavity due to disorders or disease or being a result of side effect of chemical or radiation therapy, or patients in need of remineralization of the teeth due to e.g. caries or aiming at an increased oral health in general.

Dental caries is furthermore a common and undesirable condition, e.g. in the elderly population wherein root surface lesions and recurrent carious lesions are common. Thus, also in respect of treating and preventing dental caries, the present invention would be beneficial.

**Detailed description of the invention**

The present invention will now be described in more detail with reference to figures and examples. The following description and examples intends to illustrate the present invention, and should in no way be considered limiting. Furthermore, the skilled person will acknowledge that various modifications may be introduced without departing from the scope of the invention. Accordingly, other embodiments of the present invention which are within the abilities of the skilled person are to be understood to be within the scope of the claimed invention.

The term "supersaturated" is to be understood to mean a solution comprising calcium and phosphate ions, and wherein the concentration of said ions are higher than the concentration of said ions presented in a saturated solution thereof.
The source of phosphate used in the dry component (b) of the two component preparation according to the present invention may be in the form of pharmaceutically acceptable salts of phosphates, such as e.g. sodium phosphates, potassium phosphate or ammonium phosphates. According to one embodiment, disodium hydrogen phosphate dodecahydrate (Na₂HP₄O₆ x 12 H₂O) is used as the phosphate source in component (b) of the two component preparation according to the present invention. According to yet another embodiment of the present invention, sodium phosphate hydrogen dihydrate (NaH₂PO₄ x 2 H₂O) is used as the source of phosphate in component (b). According to yet another embodiment, a mixture of Na₂HP₄O₆ x 12 H₂O and NaH₂PO₄ x 2 H₂O is used as the phosphate source in component (b).

According to a one aspect of the invention, components (a) and (b) may be separately dissolved in water, and thereafter mixed together into the final supersaturated solution. According to another aspect, the two components may be directly dissolved into the same container of water.

According to the embodiment in which the components are dissolved separately, the amount of calcium chloride hexahydrate component (a) is sufficient to provide, upon dissolution of component (a), a concentration of calcium ions in a range of from about 4 mM to about 80 mM, such as e.g. from about 4 mM to about 40 mM, or such as from about 4 mM to about 20 mM, or about 10 mM.

Upon mixing of the two solutions obtained after separately dissolving components (a) and (b), (or according to the aspects in which the two components are directly dissolved into the same container of water), the concentration of calcium ions provided in the obtained supersaturated solution is in the range of about 2 to about 40 mM, such as e.g. 2 mM to about 21 mM, such as e.g. about 2.5 to about 16 mM.

At around neutral pH the concentration of calcium ions is suitably in the range of from 2.5mM to about 10 mM, such as e.g. 3mM to 5 mM, for example about 3.87, 4.5 or 5mM.

According to the embodiment in which the components are dissolved separately, the amount of phosphate in component (b) is sufficient to provide, upon dissolution of component (b) in water, a concentration of phosphate ions in a range of about 1 mM to about 64 mM, such as e.g. 2 mM to about 40 mM, e.g. such as 3 to about 20 mM, such as e.g. 4 mM to about 12 mM.

Upon mixing of the two solution obtained after separately dissolving components (a) and (b), (or according to the aspects in which the two components are directly dissolved into the same container of water), the concentration of phosphate ions provided in the obtained supersaturated solution is in the range of about 0.5mM to about 32 mM, such as e.g. 1 mM to about 20 mM, such as e.g. about 1.5 to about 10
mM. At around neutral pH, the concentration of phosphate is suitably in the range of from about 2 to about 6 mM, such as e.g. 2 to 4 mM, for example 2, 3, 3.4 or 3.87 mM. Especially suitable is when the concentration of phosphate ions is around 2.7 to 3.4 mM, for example 2.96 mM.

The pH of the super saturated solution obtained after dissolution of powder components (a) and (b) and upon mixing thereof is within the area from about 5 to about 8, more preferably from about 6 to about 7.5, such as about 6.5 to about 7.5; especially preferable is when the pH is about neutral such as 7.0 +/- 0.2.

Alternately, a pH adjuster could be used to provide the desired pH.

The term "stabilizing agent" as used herein is a compound or compounds which facilitate the dissolution of calcium and phosphate upon dissolution of dry components (a) and (b). The stabilizer agent contained in the dry components (a) and (b) of the present two component preparation may be one or more alkali metals such as e.g. earth alkali halides, such as e.g. sodium chloride or potassium chloride, preferably sodium chloride. Ammonium salts such as e.g. ammonium chloride may also be used as a stabilizing agent according to the present.

The amount of stabilizer in dry components (a) and (b) is sufficient to, upon dissolution, allow the use of calcium and phosphate which are higher than the amount obtained in a saturated solution of calcium and phosphate ions. In case of sodium chloride, the amount of sodium chloride should provide an isotonic solution due to the aim of avoiding bad taste, possible irritation and/or pain in the oral cavity caused by sodium chloride.

The concentration of sodium chloride upon dissolution of dry components (a) and (b) in the final mouth rinse solution, is according to one aspect of the present invention in a range of about 40 mM to about 400 mM, such as e.g. 80 mM to 200 mM, such as about 100 mM.

The two component preparation according to the present invention may also comprise fluoride, in which is preferably comprised in component (b).

In case it is of importance to facilitate the healing of wound or fissures in the oral cavity, zinc may as well be added to component (a) and/or component (b), preferably zinc is added to component (a).

The administration regime of a mouth rinse solution obtained by the dissolution of dry components (a) and (b) of the present two component preparation and this is the same as for super saturated mouth rinse preparation well known to the skilled person, e.g. such as for Caphosol™ as described in US 6387352 and US 5993785 (the entire contents of which are hereby incorporated by reference as if repeated verbatim herein for establishing such regime).
The present preparation may be used together with other dental health products and treatment methods, such as e.g. tooth brushing, methods and preparations for the application of fluoride, salivary gland stimulation methods and preparations etc.

Examples

The present invention will now be described in more detail with reference to examples, which are not to be contemplated as restrictive or limiting to the scope of the present invention. One skilled in the art will recognize that the specific amounts of the ingredients may be adjusted respectively to arrive at a supersaturated solution having ion concentrations in the intended ranges.

Example 1 Manufacturing of a two component preparation.

Calcium chloride hexahydrate and sodium chloride may be weighed out in the amounts given in table 1 and mixed to provide powder mixture (a).

Sodium phosphate and sodium chloride may be weighed out in the amounts given in table 1 and mixed to provide powder mixture (b).

The powder mixture (a) and (b) may be filled in airtight, single dose containers to be used for the preparation of two separate solution which upon mixing provide a mouth rinse solution ready to use.

Example 2 Preparation of a super saturated solution

A powder mixture of calcium chloride hexahydrate and sodium chloride and a powder mixture of sodium phosphate and sodium chloride as provided in table 1 were added to 50 ml water respectively, to yield a solution (a) comprising calcium ions and a solution (b) comprising phosphate ions. The two solutions were then combined to yield the final super saturated mouth rinse solution.

Normal tapwater can be used provided the water is of low hardness. The amounts of the solid refer to the w/w % and correspond to the mixed volume of 100 ml. The amount of solids has been tested against the already available CaphosolTM product in order to verify the concentration of the compounds in the final solution. If a smaller volume is needed the amount of solids can be reduced accordingly. Here we have given amounts corresponding to 100 ml final solution.

CaphosolTM provides 0.052% (w/w) of CaCl calculated as without crystal water. In the solid preparation according to the present invention we use CaCl 6H2O. Accordingly we need an amount of 103 mg CaCl 6 H2O to give the same
concentration as the CaphosolTM solution in 100 ml. The amounts of the phosphates as solids will preferably be the same as prescribed in the CaphosolTM product.

Example 3 Manufacturing of a two component effervescent tablet.

Calcium chloride hexahydrate and sodium chloride may be weighed out in the amounts given in table 1 and mixed to provide a dry component (a).

Sodium phosphate and sodium chloride may be weighed out in the amounts given in table 1 and mixed to provide a dry component (b).

The components (a) and (b) may be mixed with binders and effervescent agents and formed into a tablet, with component (a) arranged in one segment of the tablet, component (b) arranged in a second segment of the tablet, with a layer of inert material separating the two components. Alternately, the components may be arranged as two separately packaged effervescent tablets.

Table 1: Amounts and ingredient of a two component preparation

<table>
<thead>
<tr>
<th>Two component preparation</th>
<th>Amount of ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Powder mixture A</td>
<td></td>
</tr>
<tr>
<td>Calcium chloride x 6H₂O</td>
<td>103 mg</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>300 mg</td>
</tr>
<tr>
<td>Powder mixture B</td>
<td></td>
</tr>
<tr>
<td>Na₂HP0₄ x 12 H₂O</td>
<td>81 mg</td>
</tr>
<tr>
<td>NaH₂P0₄ x 2 H₂O</td>
<td>12 mg</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>300 mg</td>
</tr>
</tbody>
</table>
Table 2: Various concentrations of dry components

The amounts of the ingredients were varied, and the length of time the components remained in supersaturated solution was observed.

<table>
<thead>
<tr>
<th>Solution</th>
<th>parallel 1</th>
<th>parallel 2</th>
<th>parallel 3</th>
<th>parallel 4</th>
<th>parallel 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time until cloudy</td>
<td>Time until cloudy</td>
<td>Time until cloudy</td>
<td>Time until cloudy</td>
<td>Time until cloudy</td>
</tr>
<tr>
<td>Solution 1</td>
<td>became cloudy immediately</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solution 2</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
</tr>
<tr>
<td>Solution 3</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
</tr>
<tr>
<td>Solution 4</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
</tr>
<tr>
<td>Solution 5</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
</tr>
<tr>
<td>Solution 6</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
<td>&gt; 2 hours</td>
</tr>
</tbody>
</table>

pH solution 2, average of five parallels: 7.2

Solution 1: same as solution 2, but no added NaCl

Solution 2: Original solution
- 103 mg CaCl₂·6H₂O
- 30 mg NaCl in 50 ml water
- 1.8 mg Na₂HPO₄·12H₂O
- 30 mg NaCl in 50 ml water

Solutions mixed to give 100 ml final solution

Solution 3: Phosphate salt increased by 5%
- 103 mg CaCl₂·6H₂O
- 30 mg NaCl in 50 ml water
- 85.1 mg Na₂HPO₄·12H₂O
- 30 mg NaCl in 50 ml water

Solutions mixed to give 100 ml final solution

Solution 4: Calcium salt increased by 5%
- 108.2 mg CaCl₂·6H₂O
- 30 mg NaCl in 50 ml water
- 81 mg Na₂HPO₄·12H₂O
- 30 mg NaCl in 50 ml water

Solutions mixed to give 100 ml final solution

Solution 5: Phosphate salt increased by 10%
- 103 mg CaCl₂·6H₂O
- 30 mg NaCl in 50 ml water
- 89.1 mg Na₂HPO₄·12H₂O
- 30 mg NaCl in 50 ml water

Solutions mixed to give 100 ml final solution

Solution 6: Calcium salt increased by 10%
- 113.2 mg CaCl₂·6H₂O
- 30 mg NaCl in 50 ml water
- 81 mg Na₂HPO₄·12H₂O
- 30 mg NaCl in 50 ml water

Solutions mixed to give 100 ml final solution
CLAIMS

1. A composition for preparing a mouth rinse in the form of a supersaturated aqueous solution of calcium and phosphate ions, characterized in that the composition comprises:
   a. A first dry component comprising calcium chloride hexahydrate and a stabilizer,
   b. A second dry component comprising phosphate and a stabilizer.

2. The composition according to claim 1, wherein the stabilizer in the dry components is an alkali metal.

3. The composition according to claim 2, wherein the stabilizer in the dry components is sodium chloride.

4. The composition according to one of the preceding claims, wherein the second dry component comprises disodium hydrogen phosphate dodecahydrate (Na$_2$HPO$_4$ x 12 H$_2$O).

5. The composition according to one of the preceding claims, wherein the second dry component comprises sodium phosphate hydrogen dihydrate (NaH$_2$PO$_4$ x 2 H$_2$O).

6. The composition according to one of the preceding claims, wherein the second dry component comprises a combination of disodium hydrogen phosphate dodecahydrate (Na$_2$HPO$_4$ x 12 H$_2$O) and sodium phosphate hydrogen dihydrate (NaH$_2$PO$_4$ x 2 H$_2$O).

7. The composition according to one of the preceding claims, further comprising instructions instructing an end user to mix the first and second dry components together into a predetermined quantity of water sufficient to arrive at a supersaturated solution.

8. The composition according to one of the preceding claims, wherein the dry components are provided in sufficient amounts such that, upon mixing of two solutions obtained after separately dissolving dry components (a) and (b) in a predetermined amount of water, or upon directly dissolving the two dry components into the same container of water, a supersaturated solution is obtained, the concentration of calcium ions provided in the obtained supersaturated solution being in the range of about 2 to about 40 mM.

9. The composition according to claim 8, wherein the concentration of calcium ions is in the range of about 2 mM to about 21 mM.

10. The composition according to claim 8, wherein the concentration of calcium ions is in the range of about 2.5 to about 16 mM.
11. The composition according to claim 8, wherein the concentration of calcium ions is in the range of, at around neutral pH, from 2.5mM to about 10 mM.

12. The composition according to claim 8, wherein the concentration of calcium ions is in the range of, at around neutral pH, from 3mM to 5 mM, for example about 3.87, 4.5 or 5mM.

13. The composition according to one of the preceding claims, wherein the dry components are provided in sufficient amounts such that, upon mixing of two solutions obtained after separately dissolving dry components (a) and (b) in a predetermined amount of water, or upon directly dissolving the two dry components into the same container of water, a supersaturated solution is obtained, the concentration of phosphate ions provided in the obtained supersaturated solution being in the range of about 0.5mM to about 32 mM.

14. The composition according to claim 13, wherein the concentration of phosphate ions is in the range of 1mM to about 20 mM.

15. The composition according to claim 13, wherein the concentration of phosphate ions is in the range of about 1.5 to about 10 mM.

16. The composition according to claim 13, wherein the concentration of phosphate ions is in the range of, at around neutral pH, from 2 to about 6 mM, preferably from 2 to 4mM, for example 2, 3, 3.4 or 3.87 mM, and more preferably from around 2.7 to 3.4 mM, for example 2.96 mM.

17. The composition according to one of the preceding claims, wherein the pH of the supersaturated solution is from about 5 to about 8.

18. The composition according to one of the preceding claims, wherein the of sodium chloride upon dissolution of dry components (a) and (b) in the final mouth rinse solution, is in the range of about 40 mM to about 400 mM, such as e.g. 80 mM to 200 mM, such as about 100 mM.

19. The composition according to one of the preceding claims, wherein the predetermined amount of water in the final solution is 100ml.

20. The composition according to claim 19, wherein the amount of calcium chloride hexahydrate is from 103 mg to 113.2mg, the amount of disodium hydrogen phosphate dodecahydrate is from 81 mg to 89.1 mg, and the amount of sodium phosphate hydrogen dihydrate is from 12 mg to 13.2 mg.
21. The composition according to claim 19, wherein the amount of calcium chloride hexahydrate is 103 mg, the amount of disodium hydrogen phosphate dodecahydrate is 81 mg, and the amount of sodium phosphate dihydrate is 12 mg.

22. The composition according to one of the preceding claims, wherein the dry components are packaged separately in individual packets.

23. The composition according to one of the preceding claims, wherein the dry components are formed into and separately packaged as individual tablets.

24. The composition according to one of the preceding claims, wherein the dry components are formed into and packaged as a single effervescent tablet.

25. The composition according to one of the preceding claims further comprising fluoride.

26. The composition according to one of the preceding claims, wherein the components remain in supersaturated solution for greater than two hours.

27. A kit comprising unit dosage containers comprising a powder mixture comprising calcium chloride hexahydrate and a stabilizer and separated there from unit dosage containers comprising a powder mixture comprising phosphate and a stabilizer, and optionally fluoride and an instruction manual instructing the mixture of the powder mixtures in a sufficient amount of water to arrive at a supersaturated solution of calcium and phosphate ions.

28. The kit according to claim 27, wherein the unit dosage containers are packets.

29. The kit according to claim 27, wherein the unit dosage containers are tablets.