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Description

The present invention relates to oral hygiene compositions. More particularly, the present invention relates to oral hygiene compositions which prevent and control mouth odour, calculus, plaque and caries and contain active zinc ions and fluoride ions. These compositions are also effective at preventing gingivitis and periodontal disease.

The use of soluble fluoride salts, such as stannous fluoride, sodium monofluorophosphate and sodium fluoride, to reduce the incidence of dental caries in the general population is a well-known and ongoing endeavour. The administration of these fluoride compounds takes many forms, including the fluoridation of drinking water, professional treatment by dentists and incorporation in oral hygiene compositions such as dentifrices and mouth-rinses.

It is also known that zinc plays a role in dental care. For example, in US-A-4 160 821 there is disclosed a composition for treating gingivitis comprising a vehicle containing a high concentration of glycerol and a zinc salt, such as zinc chloride, that is soluble in the glycerol.

In an article entitled "Inhibition of Plaque Growth by Zinc Salts," Journal of Periodontal Research, Vol. 18, pp. 634-642, 1983, Harrap et al. reported that solutions of zinc salts reduced plaque by 30% along the gingival margin. In "Effect of Some Polyvalent Cations on Plaque Formation In Vivo", Scandinavian Journal of Dental Research, Vol. 186, pp. 103-107, 1978, it is indicated that mouth rinses containing either $ZnCl_2$, $AlCl_3$, $MgCl_2$, SnF_2 or $SnCl_2$ exhibited significant plaque reducing activity. An oral rinse containing 1.0% zinc salts (as the phenolsulphonate) or 0.125% zinc complex with tribromsalan was found clinically to reduce mean calculus scores by about 60% and 53% respectively, in two consecutive three-month trials as reported by Picozzi et al. in an article entitled, "Calculus Inhibition in Humans", Journal of Periodontology, Volume 43, pp. 692-695, 1972. Zinc compounds (as 1% zinc phenolsulfonate and 0.125% zinc tribromsalan) formulated in an aqueous mouthwash significantly delayed the development of gingivitis in a test group compared to a placebo by Fischman et al., Journal of Periodontology, Vol. 44, pp. 535-539, 1975.

In GB-A-1 373 003, there is disclosed a dentifrice composition having activity against plaque and calculus on a tooth surface comprising a sparingly soluble zinc salt which is defined as a zinc salt of an acid, other than zinc fluoride or its hydrates, having a water solubility greater than that of zinc phosphate and less than 1 gram of zinc per 100 ml of water at 20 °C and a mixture of detergents. The dentifrice may also contain a compatible abrasive such as alumina and other conventional toothpaste ingredients.

US-A-4 146 606 relates to a pharmaceutical composition for dental use that can, inter alia, suppress dental caries, this composition comprising a strontium compound, a zinc compound, tannin and, optionally, a fluorine compound.

US-A-4 138 477 discloses a composition to prevent and control mouth odour, which is also said to be effective in preventing calculus, plaque, caries and periodontal disease, containing as the essential agent a zinc-polymer complex formed by the reaction or chelation of a zinc compound with an anionic polymer containing carboxylic, sulfonic and/or phosphoric acid radicals. The composition may also include, inter alia, a fluorine-containing compound that protects the teeth against decay.

US-A-4 396 599 (equivalent to EP-A-0 075 446) describes anticaries compositions including dentifrices containing a fluoride compound and a zinc compound with a ratio of zinc ion to fluoride ion of at least about 7:1 by weight.

EP-A-0 074 082 discloses a stable oral composition containing zinc salicylate, zinc lactate or zinc gluconate in combination with an tonic fluoride salt.

GB-A-2 052 978 discloses an oral composition having anticalculus and antiplaque activity wherein zinc ions are kept in a biologically active solution at a pH of 4.5 to 8 by the addition of glycine.

The present invention provides an oral hygiene composition consisting essentially of:

an effective concentration of a source of fluoride ion;

an effective concentration of a source of zinc ion;

a buffering agent; and

an oral hygiene vehicle,

in which:

the source of fluoride ion is sodium fluoride, potassium fluoride, lithium fluoride, aluminium fluoride, zinc fluoride, stannous fluoride, sodium monofluorophosphate, acidulated phosphate fluoride, ammonium fluoride, ammonium bifluoride, titanium tetrafluoride or amine fluoride;

the source of zinc ion is zinc chloride, zinc sulphate or zinc thiocyanate;

the buffering agent is maleic acid, aspartic acid, succinic acid, glucuronic acid, glucuronic acid lactone, fumaric acid or sodium glutamate; and

the composition has a pH of 3.5 to 6.0.

Preferred features of the invention are described in the claims dependent on claim 1.

The present invention provides improved oral hygiene compositions which prevent and control mouth odour, calculus, plaque, caries and gingivitis. The oral hygiene compositions of the present invention may minimize astringent taste and exhibit good fluoride and zinc ion bioavailability.

The fluoride ion concentration can be up to 4.0% by weight. The zinc ion concentration can be up to 30.0% by weight. While higher concentrations of both zinc and fluoride ions could be used, no particular advantage would be afforded thereby, and there are some contraindications in the literature concerning the safety of higher concentrations of fluoride and zinc ions.

The ratio of zinc ions to fluoride ions can range from 0.05:1 to 25:1, preferably from about 5:1 to 15:1. The fluoride ions are taken up by the dental enamel and render the teeth less susceptible to caries attack and dental decay by increasing the hardness of the enamel or reducing the enamel solubility. The zinc ions help to prevent the formation of tartar, oral malodour and gingivitis.

The choice of specific buffering agents is essential to the performance of the compositions of the present invention and are required to maintain the acid pH and prevent precipitation of the zinc ion. The buffering agent should be used in an amount of from about 0.01 to 10.0%, preferably about 0.05 to 5.0% is a preferred buffering agent. The buffering agents which can be utilized are maleic acid, aspartic acid, succinic acid, glucuronic acid, glucuronic acid lactone, sodium glutamate and fumaric acid. Other organic acids and salts such as lactic acid, adipic acid and tartaric acid which would be expected to perform in the sane manner have proved to be unsatisfactory.

In order to achieve the desired results of the compositions of the present invention, the pH should be maintained between 3.5 and 6.0. This permits the fluoride ions and zinc ions to remain in solution and not precipitate out thereby permitting them to have their desired effect. This can best be achieved by adjusting the pH to the desired range by the addition of a combination of acid saccharin and sodium saccharin in an amount of from about 0.01 to 5.0%, preferably 0.1 to 2.0%. If the sodium salt or acid is utilized alone, the pH can be adjusted by the addition of an appropriate acid or base. The sodium saccharin and saccharin should be in a ratio of from about 20:1 to 2:1, preferably about 7:1.

Suitable pharmaceutically acceptable oral hygiene vehicles that may be used alone or in combination in the compositions of the present invention include glycerol, water, ethanol, polyethylene glycol, propylene glycol, sorbitol and the like. Other vehicles may be used if compatible with the other ingredients in the compositions.

If the compositions of the present invention are in the form of a dentifrice, they should also contain a suitable abrasive. The abrasive should be such that it does not harm the enamel or dentin while being capable of cleaning and polishing the teeth as well as being compatible with the fluoride ions and zinc ions. Preferred abrasives include the silica abrasives. Silica abrasives which are useful are those having an average particle size of from about 0.1 to 45 microns, preferably from about 4 to 20 microns; having a pH from about 3.5 to 9.0; and are usually in the form of precipitated silica, silica xerogels or silica hydrogels. The preferred silica abrasives are the silica hydrogels available from W. R. Grace under the tradename "Hydrous Silica Gel". The preferred silica hydrogels have a water content of 15-60% and a pH of about 4.5. The low pH of the silicas helps to keep the fluoride ions and zinc ions soluble and therefore available and also helps in keeping the pH of the formulations stable. Other suitable silica abrasives include the silica xerogels described in U.S. Patent No. 4,100,269 and the precipitated silica materials described in U.S. Patent No. 3,862,307 available from Huber Corporation under the tradename "Zeodent".

The silica abrasives should be present in the dentifrice compositions from about 5.0 to 70.0%, preferably about 10.0 to 40.0%. These materials are compatible with the zinc and fluoride ions in such formulations and serve as cleaning and polishing agents.

The dentifrice formulations should also contain specific polymers which are useful as binders and thickeners in the compositions. These include the non-ionic water-soluble polymers which are compatible with the other ingredients in the formulation. Hydroxyethylcellulose polymers are available from Hercules Inc. under the tradename "Natrosol" and have been found to be preferred in the compositions for maintaining viscosity over a wide pH range. These non-ionic polymers should be present in the compositions in an amount of from about 0.03 to 10.0%, preferably from about 0.1 to 3.0%.

It is often desirable for formulation purposes to use more than one binder to achieve the desired results. In addition to hydroxyalkylcellulosic binders, other binders can be selected from xanthan gum, carrageenan, gum karaya, gum arabic and gum tragacanth. Xanthan gum is preferred and can be utilized in an amount of from about 0.02 to 5.0%, preferably 0.1 to 3.0%.

Another component in dentifrice compositions is a humectant. The humectant serves to keep the dentifrice compositions from hardening upon exposure to air and also imparts a desirable sweetness to the formulations to minimize the astringency ascribed to the zinc chloride. The humectant, on a pure humectant

basis, generally comprises from about 5.0 to 80.0%, preferably from about 8.0 to 50.0% by weight of the total compositions. Suitable humectants include edible polyhydric alcohols such as glycerine, sorbitol, xylitol and propylene glycol. Mixtures of glycerine and sorbitol are especially preferred.

Water is another essential component of dentifrice compositions. Water employed in the preparation of commercially suitable dentifrices should preferably be deionized and free of impurities. Water comprises from about 0.05 to 70.0%, preferably from about 15.0 to 50.0% by weight of the formulations. These amounts of water include the free water which is added plus that which is introduced with other materials.

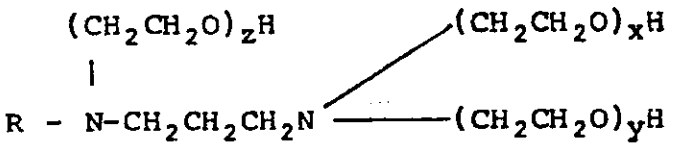
Another ingredient of dentrifice compositions is a suitable surface-active agent or detergent. Suitable surface-active agents are those that are reasonably stable, foam through the pH range and are compatible with the zinc and fluoride compounds as well as the other components. These agents are usually water-soluble, organic compounds and may be anionic, nonionic or cationic in nature. Such materials are well-known and include, for example, the water-soluble salts of high fatty acid monoglyceride-monosulfates such as sodium coconut acid monoglyceride monosulfate; higher alkyl sulfates such as sodium lauryl sulfate, alkyl aryl sulfonate such as sodium dodecyl benzene sulfonate, higher fatty acid esters of 1,2-dihydroxypropane sulfonate, and sodium salts of the coconut fatty acid amide of N-methyltaurine. The latter is particularly preferred since it has been found to minimize the astringency of zinc chloride. Particularly useful are the nonionic block copolymers derived from the condensation of polyethylene glycol and polypropylene glycol. These block copolymers are available from Wyandotte Chemical Corp. under the tradename "Pluronic". These block copolymers are available in liquid, paste or solid form. The preferred nonionic block copolymers are the solid materials such as Pluronic F-85, Pluronic F-108 and Pluronic F-127.

Another preferred nonionic detergent is the cogeneric mixture of conjugated polyoxybutylene-polyoxyethylene described in U.S. Patent No. 4,323,552 sold under the tradename "Butronic" by BASF Wyandotte Corporation. Butronic Polyol L-1 and Butronic Polyol R-1 are particularly preferred.

The Pluronic and Butronic nonionic surface-active agents have been found to minimize the astringency of the zinc chloride and can be present in the amount of from about 0.5 to 10%, preferably about 1.0 to 5.0%.

Other nonionic surface-active agents which may be employed are the condensates of sorbitan monostearate with approximately 20 moles of ethylene oxide. Amphoteric agents include the quaternized imidazole derivatives which are available under the tradename "Miranol" such as Miranol C_2M, from the Miranol Chemical Company.

Cationic surface-active agents can also be used. These compounds have detergent properties as well as germicidal and antibacterial properties. Examples of suitable cationic detergents are benzyl ammonium chloride, benzyl dimethyl stearylammonium chloride, tertiary amines having one fatty alkyl group of from 1-18 carbon atoms and two (poly)oxyethylene groups attached to the nitrogen and salts thereof with acids, and compounds of the structure:



where R is a fatty alkyl group and can have from about 12 to 18 carbon atoms, and x, y, and z total 3 or higher, as well as salts thereof with mineral or organic acids, may also be used. About 0.5% to 15% by weight of these cationic surface-active agents can be used in dentifrice compositions.

In addition to the above described components, the dentifrices can contain a variety of optional conventional dentifrice ingredients. Such optional ingredients include preservatives, flavoring agents, sweetening agents, coloring agents and pigments.

Suitable flavoring agents include oil of wintergreen, oil of peppermint, oil of spearmint, oil of sassafras, and oil of clove. Sweetening agents which can be used include saccharin, dextrose, levulose, aspartame, D-tryptophan, dihydrochalcones and sodium cyclamate. Flavoring agents are generally utilized in dentifrices at levels of from about 0.01% to 2% by weight and sweetening agents at levels of from about 0.05% to about 2% by weight.

These dentifrice compositions are prepared by mixing together the components by conventional means. Once prepared, the compositions have a pH of from about 3.5 to 6.0, when said compositions are slurried with water in a 3:1 weight ratio of water to composition. These dentifrice compositions are used in conventional manner, i.e., the compositions or slurries are brushed onto dental surfaces and subsequently

rinsed away. During use of the dentifrices in this manner, pastes or slurries generally contact dental surfaces for at least about 30 seconds. More preferably, such pastes or slurries contact dental surfaces for at least about 60 seconds.

While the previous discussions have been directed to dentifrice compositions, the present invention may also encompass compositions in the form of a mouthwash, gel, powder, solution, varnish, lozenge, chewing gum, slow release device or other form suitable for oral application. Any pharmaceutically acceptable material, such as those ordinarily used in such oral compositions, that are comparable with the zinc and fluoride ions may be employed in the compositions of this invention.

Specific embodiments of the present invention are illustrated by the following Examples. It will be understood, however, that the invention is not confined to the specific limitations set forth in the individual Examples but rather to the scope of the appended claims. All the Examples, apart from Example VI, are outside the scope of the invention and use only sodium gluconate as a buffering agent. However, as can be seen from Example VI, all the buffering agents as claimed give comparable results to those of sodium gluconate.

All percentages used herein are by weight unless otherwise designated.

Example I

An opacified dentifrice having the following composition is formulated:

	% w/w
sodium fluoride	0.22
zinc chloride	2.00
sorbitol (70% aqueous)	35.00
glycerin	10.00
hydrated silica	23.00
sodium ethyl cocoyl taurate	3.75
xanthan gum	1.00
hydroxylethylcellulose	1.00
sodium gluconate	0.80
titanium dioxide	0.80
sodium saccharin	0.70
saccharin	0.10
sodium benzoate	0.20
flavor	1.30
deionized water	q.s. to 100.00

EXAMPLE II

Another opacified dentifrice having the following conposition is formulated:

	% w/w
sodium fluoride	0.22
zinc chloride	2.00
sorbitol (70% aqueous)	35.00
glycerin	10.00
hydrated silica	23.00
Pluronic F-85 (a tradename of Wyandotte Corp. for conjugated polyoxyethylenes-polyoxypropylenes)	3.00
xanthan gum	1.00
hydroxyethylcellulose	1.00
titanium dioxide	0.80
sodium gluconate	0.80
sodium saccharin	0.70
saccharin	0.10
sodium benzoate	0.20
flavor	1.30
deionized water	q.s. to 100.00

EXAMPLE III

Another opacified dentifrice having the following composition is formulated:

	% w/w
sodium fluoride	0.22
zinc chloride	0.50
sorbitol (70% aqueous)	40.00
glycerin	15.00
hydrated silica	23.00
polyethylene glycol	5.00
sodium methyl cocoyl taurate	3.75
xanthan gum	0.50
hydroxyethylcellulose	0.50
sodium saccharin	0.50
saccharin	0.30
sodium gluconate	0.27
sodium benzoate	0.20
titanium dioxide	0.20
flavor	1.00
deionized water	q.s. to 100.00

EXAMPLE IV

A gel dentifrice having the following composition is formulated:

	% w/w
sodium fluoride	0.22
zinc chloride	0.50
sorbitol (70% aqueous)	50.00
glycerin	5.00
hydrated silica	23.00
polyethylene glycol	5.00
sodium methyl cocoyl taurate	3.75
xanthan gum	0.50
hydroxyethylcellulose	0.50
sodium gluconate	0.27
sodium saccharin	0.50
saccharin	0.15
sodium benzoate	0.20
flavor and coloring agents	0.70
deionized water	q.s. to 100.00

EXAMPLE V

Comparative studies were conducted on rats utilizing the composition described in Example III, a commercial dentifrice (Dentifrice A) containing 0.5% zinc citrate, 0.8% sodium monofluorophosphate, having a pH of 7.85 and no buffer system, as well as another commercial dentifrice (Dentifrice B) which contains no zinc chloride, 0.22% sodium fluoride, a phosphate buffer, and has a pH of 7.05. In these studies, each group consisted of thirty male Wistar rats, approximately 50 grams each and caged by pairs in raised wire cages. At nineteen days of age the animals were weighed and randomly distributed into groups. The animals were fed NIDR Diet No. 5000 and were given deionized water to drink ad libitum. Approximately 0.15 of each preparation was applied with a cotton applicator per jaw. Treatments were applied twice per day, seven days per week, for three weeks. Immediately prior to sacrifice, all animals were observed for any visual signs of ill health and individually weighed. At the end of three weeks, the animals were sacrificed; the heads cleaned, the jaws and teeth sectioned, stained and scored for dental caries by the Keyes Method. The data were then analyzed for significant differences between means, for both the number and severity of carious lesions. The results are shown in Table I below:

TABLE I

Rat Caries Studies

Formula	% Zinc Salt	Sodium Gluconate Buffer	pH	% Fluoride Salt	% Red. in Number Enamel Lesions	% Red. Severity Enamel Lesions
Example III	0.5% $ZnCl_2$	Yes	4.75	0.21% NaF	26.0	27.0
Dentifrice A	0.5% Zinc Citrate	No	7.85	0.8% NaMFP	9.0	5.0
Dentifrice B	None	No	7.1	0.21% NaF	1.0	6.0

These results above clearly show that the composition of Example III is significantly superior to the two commercial formulations in reducing both the number and severity of dental lesions.

EXAMPLE VI

Solutions each contain 35.00 g. sorbitol, 10.00 g. glycerol, 2.00 g. zinc chloride, 0.22 g. sodium fluoride and 16.00 g. deionized water are prepared. To each of these solutions various organic acids and salts are

added in varying amounts and mixed resulting in clear solutions within the desired pH range. The solutions are left for one week at 60°C and then reviewed and noted as either clear, hazy or exhibiting a precipitate. The results are shown below in Table II:

TABLE II

Organic Acid/Salt	conc. (gm.)	pH (init.)	One Week Aging
(No organic acid/salt)	0	5.50	precipitate
adipic acid	0.10	4.00	precipitate
glucuronic acid	0.10	4.45	clear
fumaric acid	0.10	4.35	clear
malic acid	0.10	4.40	haze
lactic acid	0.10	4.65	precipitate
aspartic acid	0.10	4.85	clear
succinic acid	0.10	4.65	clear
tartaric acid	0.10	4.60	precipitate
maleic acid	0.10	4.60	clear
glucuronic acid lactone	0.10	4.85	clear
gluconic acid (50%)	0.20	4.00	clear
sodium gluconate	0.80	5.35	clear
sodium glutamate	0.10	4.85	clear

The above results demonstrate that without any organic acid/salt a precipitate is formed. However, not all organic acids are useful in the compositions of the present invention. Those acids that result in the formation of a precipitate or haze (start of precipitate) would not be useful since they would result in a reduction in the available fluoride ions and zinc ions.

EXAMPLE VII

A tooth powder composition is prepared according to conventional means containing the following ingredients:

	% w/w
silica hydrogel	96.21
zinc chloride	0.50
sodium flouride	0.22
sodium gluconate	0.27
synthetic sweetener (saccharin, aspartame)	0.50
sodium methylcocoyltaurate	1.50
flavoring	0.80

EXAMPLE VIII

An oral hygiene spray is prepared according to conventional means containing the following ingredients:

	% w/w
ethanol	15.00
zinc chloride	0.50
sodium fluoride	0.05
sodium gluconate	0.27
saccharin	0.50
flavoring	1.00
propellant	5.00
deionized water	q.s. to 100.00

EXAMPLE IX

A mouthrinse composition is prepared according to conventional means containing the following ingredients:

	% w/w
ethyl alcohol (190 proof)	6.00
Pluronic F-127	1.75
zinc chloride	0.25
sodium fluoride	0.05
sodium gluconate	0.15
glycerin	8.00
sodium saccharin	0.25
saccharin	0.30
cetylpyridinium chloride	0.10
flavoring and color	2.50
deionized water	q.s. to 100.00

EXAMPLE X

A lozenge composition is prepared according to conventional means containing the following ingredients:

	% w/w
sorbitol powder	74.63
corn syrup	15.00
zinc chloride	0.50
sodium fluoride	0.22
flavor and color	1.15
sodium gluconate	0.30
synthetic sweeteners	0.20
tableting lubricant	5.00
deionized water	3.00

EXAMPLE XI

A chewing gum composition is prepared according to conventional means containing the following ingredients:

	% w/w
gum base	30.00
sorbitol	48.98
corn syrup	15.00
flavor	1.50
zinc chloride	0.50
sodium fluoride	0.22
sodium gluconate	0.30
gum tragancanth	0.50
deionized water	3.00

Claims

1. An oral hygiene composition consisting essentially of:
an effective concentration of a source of fluoride ion;
an effective concentration of a source of zinc ion;
a buffering agent; and
an oral hygiene vehicle,
and having a pH of 3.5 to 6.0,
characterised in that:
the source of fluoride ion is sodium fluoride, potassium fluoride, lithium fluoride, aluminium fluoride, zinc fluoride, stannous fluoride, sodium monofluorophosphate, acidulated phosphate fluoride, ammonium fluoride, ammonium bifluoride, titanium tetrafluoride or amine fluoride;
the source of zinc ion is zinc chloride, zinc sulphate or zinc thiocyanate; and
the buffering agent is maleic acid, aspartic acid, succinic acid, glucuronic acid, glucuronic acid lactone, fumaric acid or sodium glutamate.

2. The composition of claim 1 wherein the fluoride ion is present in a concentration of 0.0025 to 4.0%, preferably 0.005 to 1%, most preferably 0.02 to 0.5%, by weight.

3. The composition of claim 1 or claim 2, wherein the zinc ion is present in a concentration of 0.02 to 30%, preferably 0.05 to 10.0%, most preferably 0.1 to 5.0%, by weight.

4. The composition of any one of claims 1 to 3, wherein the buffering agent is present in a concentration of 0.01 to 10.0%, preferably 0.05 to 5.0%, by weight.

5. The composition of any of claims 1 to 4, wherein the vehicle is glycerol, water, ethanol, polyethylene glycol, propylene glycol or sorbitol.

6. A process for preparing an oral hygiene composition which comprises mixing essentially an effective concentration of a source of fluoride ion;
an effective concentration of a source of zinc ion;
a buffering agent; and
an oral hygiene vehicle, so that the composition has a pH of 3.5 to 6.0,
characterised in that:
the source of fluoride ion is sodium fluoride, potassium fluoride, lithium fluoride, aluminium fluoride, zinc fluoride, stannous fluoride, sodium monofluorophosphate, acidulated phosphate fluoride, ammonium fluoride, ammonium bifluoride, titanium tetrafluoride or amine fluoride;
the source of zinc ion is zinc chloride, zinc sulphate or zinc thiocyanate; and
the buffering agent is maleic acid, aspartic acid, succinic acid, glucuronic acid, glucuronic acid lactone, fumaric acid or sodium glutamate.

7. A process according to claim 6, wherein the vehicle is glycerol, water, ethanol, polyethylene glycol, propylene glycol or sorbitol.

8. A process according to either of claims 6 and 7, wherein the concentrations of fluoride ion, zinc ion and buffering agent are as defined in any one of claims 2 to 5.

Patentansprüche

1. Zusammensetzung zur Mundhygiene, die im wesentlichen besteht aus:

einer wirksamen Konzentration einer Fluoridionenquelle,

einer wirksamen Konzentration einer Zinkionenquelle,

einer Puffersubstanz, und

einem Mundhygienevehikel,

und die einen pH von 3,5 bis 6,0 aufweist,
dadurch gekennzeichnet, daß
die Fluoridionenquelle Natriumfluorid, Kaliumfluorid, Lithiumfluorid, Aluminiumfluorid, Zinkfluorid, Zinn-II-fluorid, Natriummonofluorophosphat, angesäuertes Phosphatfluorid, Ammoniumfluorid, Ammoniumbifluorid, Titantetrafluorid oder Aminfluorid ist,
die Zinkionenquelle Zinkchlorid, Zinksulfat oder Zinkthiocyanat ist, und
die Puffersubstanz Maleinsäure, Asparaginsäure, Bernsteinsäure, Glukuronsäure, Glukuronsäurelacton, Fumarsäure oder Natriumglutamat ist.

2. Zusammensetzung nach Anspruch 1, in der das Fluoridion in einer Konzentration von 0,0025 bis 4,0 Gew.%, vorzugsweise von 0,005 bis 1 Gew.%, am meisten bevorzugt von 0,02 bis 0,5 Gew.%, vorliegt.

3. Zusammensetzung nach Anspruch 1 oder Anspruch 2, in der das Zinkion in einer Konzentration von 0,02 bis 30 Gew.%, vorzugsweise von 0,05 bis 10,0 Gew.%, am meisten bevorzugt von 0,1 bis 5,0 Gew.%, vorliegt.

4. Zusammensetzung nach einem der Ansprüche 1 bis 3, in der die Puffersubstanz in einer Konzentration von 0,01 bis 10,0 Gew.%, vorzugsweise von 0,05 bis 5,0 Gew.% vorliegt.

5. Zusammensetzung nach einem der Ansprüche 1 bis 4, in der das Vehikel Glycerin, Wasser, Ethanol, Polyethylenglycol, Propylenglycol oder Sorbit ist.

6. Verfahren zur Herstellung einer Zusammensetzung zur Mundhygiene, die umfaßt, daß man im wesentlichen eine wirksame Konzentration einer Fluoridionenquelle,
eine wirksame Konzentration einer Zinkionenquelle,
eine Puffersubstanz und
ein Vehikel zur Mundhygiene mischt, so daß die Zusammensetzung einen pH von 3,5 bis 6,0 aufweist,
dadurch gekennzeichnet, daß
die Fluoridionenquelle Natriumfluorid, Kaliumfluorid, Lithiumfluorid, Aluminiumfluorid, Zinkfluorid, Zinn-II-fluorid, Natriummonofluorophosphat, angesäuertes Phosphatfluorid, Ammoniumfluorid, Ammoniumbifluorid, Titantetrafluorid oder Aminfluorid ist,
die Zinkionenquelle Zinkchlorid, Zinksulfat oder Zinkthiocyanat ist, und
die Puffersubstanz Maleinsäure, Asparaginsäure, Bernsteinsäure, Glukuronsäure, Glukuronsäurelacton, Fumarsäure oder Natriumglutamat ist.

7. Verfahren nach Anspruch 6, worin das Vehikel Glycerin, Wasser, Ethanol, Polyethylenglycol, Propylenglycol oder Sorbit ist.

8. Verfahren nach einem der beiden Ansprüche 6 und 7, worin die Konzentrationen der Fluoridionen, Zinkionen und der Puffersubstanz so vorliegen, wie sie in einem der Ansprüche 2 bis 5 definiert sind.

Revendications

1. Composition d'hygiène orale consistant essentiellement en :
une concentration efficace d'une source d'ion fluorure ;
une concentration efficace d'une source d'ion zinc ;
un agent tampon ; et
un véhicule d'hygiène orale,
et présentant un pH de 3,5 à 6,0,
caractérisée en ce que la source de l'ion fluorure est le fluorure de sodium, le fluorure de potassium, le fluorure de lithium, le fluorure d'aluminium, le fluorure de zinc, le fluorure stanneux, le monofluorophosphate de sodium, le fluorure de phosphate acidulé, le fluorure d'ammonium, le bifluorure d'ammonium, le tetrafluorure de titane ou le fluorure d'amine ;
la source de l'ion zinc est le chlorure de zinc, le sulfate de zinc ou le thiocyanate de zinc ; et
l'agent tampon est l'acide maléique, l'acide aspartique, l'acide succinique, l'acide glucuronique, la lactone d'acide glucuronique, l'acide fumarique ou le glutamate de sodium.

2. Composition selon la revendication 1, dans laquelle l'ion fluorure est présent en une concentration de 0,0025 à 4,0%, de préférence de 0,005 à 1% et, mieux encore, de 0,02 à 0,5% en poids.

3. Composition selon la revendication 1 ou 2, dans laquelle l'ion zinc est présent en une concentration de 0,02 à 30%, de préférence de 0,05 à 10,0% et, mieux encore, de 0,1 à 5,0% en poids.

4. Composition selon l'une quelconque des revendications 1 à 3, dans laquelle l'agent tampon est présent en une concentration de 0,01 à 10,0%, de préférence, de 0,05 à 5,0% en poids.

5. Composition selon l'une quelconque des revendications 1 à 4, dans laquelle le véhicule est le glycérol, l'eau, l'éthanol, le polyéthylène-glycol, le propylène-glycol ou le sorbitol.

6. Procédé de préparation d'une composition d'hygiène orale, qui consiste à mélanger essentiellement
une concentration efficace d'une source d'ion fluorure ;
une concentration efficace d'une source d'ion zinc ;
un agent tampon ; et
un véhicule d'hygiène orale de manière que la composition ait un pH de 3,5 à 6,0,
caractérisé en ce que :
la source d'ion fluorure est le fluorure de sodium, le fluorure de potassium, le fluorure de lithium, le fluorure d'aluminium, le fluorure de zinc, le fluorure stanneux, le monofluorophosphate de sodium, le fluorure de phosphate acidulé le fluorure d'ammonium, le bifluorure d'ammonium, le tetrafluorure de titane ou le fluorure d'amine ;
la source de l'ion zinc est le chlorure de zinc, le sulfate de zinc ou le thiocyanate de zinc ;
et
l'agent tampon est l'acide maléique, l'acide aspartique, l'acide succinique, l'acide glucuronique, la lactone d'acide glucuronique, l'acide fumarique ou le glutamate de sodium.

7. Procédé selon la revendication 6, dans lequel le véhicule est le glycérol, l'eau, l'éthanol, le polyéthylène-glycol, le propylène-glycol ou le sorbitol.

8. Procédé selon la revendication 6 ou 7, dans lequel les concentrations de l'ion fluorure de l'ion zinc et de l'agent tampon sont telles que définies dans l'une quelconque des revendications 2 à 5.

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