

CARLOS TAMAYO & ASOCIADOS
INTERNATIONAL PATENTS AND TRADEMARKS OFFICE

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SUPERINDUSTRIA Y COMERCIO
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Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Señores
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES
E. S. D.

REF: EXPEDIENTE No.00-025234
PATENTE: "COMPOSICIONES DENTIFRICAS QUE CONTIENEN ZINC..."

Estimados señores:

Con fundamento jurídico en lo dispuesto por el Artículo (44) de la Decisión (486) de la Comisión de la Comunidad Andina de Naciones (CAN) ruego a ustedes disponer lo pertinente para proceder al Examen de Patentabilidad de la Solicitud citada en la referencia, para lo cual estamos adjuntando el recibo de pago correspondiente a la tasa vigente para este caso.

En consecuencia, esperamos se surta este trámite para que el expediente siga su curso normal, hasta su concesión.

Atentamente,

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Industria y Comercio

SUPERINTENDENCIA

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***** CONSIGNACION *****

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***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01	SOLICITUDES	
		85 EXAMEN DE PATENTABILIDAD DE INVEN	335,000.00
		TOTAL :	\$ 335,000.00

SON: TRESCIENTOS TREINTA Y CINCO MIL PESOS

RESPONSABLE :

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

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United States Patent [19]

Asano et al.

[11] Patent Number: 4,568,540

[45] Date of Patent: Feb. 4, 1986

[54] ORAL HYGIENE COMPOSITIONS

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[73] Assignee: Johnson & Johnson, New Brunswick, N.J.

[21] Appl. No.: 601,765

[22] Filed: Apr. 18, 1984

[51] Int. Cl.⁴ A61K 7/16; A61K 7/18; A61K 7/24

[52] U.S. Cl. 424/52; 424/151

[58] Field of Search 424/49-58, 424/151

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U.S. PATENT DOCUMENTS

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[57] ABSTRACT

An oral hygiene composition containing an effective concentration of a pharmaceutically acceptable fluoride salt, a pharmaceutically acceptable zinc salt, a specific buffering agent, a suitable vehicle and having a pH of from about 3.5 to 6.0.

11 Claims, No Drawings

ORAL HYGIENE COMPOSITIONS

BACKGROUND OF THE INVENTION

The present invention relates to oral hygiene compositions. More particularly, the present invention relates to oral hygiene compositions which prevent and control mouth odor, 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 endeavor. 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 mouthrinses.

It is also known that zinc plays a role in dental care. For example, in U.S. Pat. No. 4,160,821 issued July 10, 1979, 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 of Plaque Formation In Vivo", Scandinavian Journal of Dental Research Vol. 186, pp. 103-107, 1978, it is indicated that mouthrinses 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 phenolsulphonate 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 Periodontology, Vol. 44, pp. 535-539, 1975.

In British Patent Specification No. 1,373,003, published Nov. 6, 1974, 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. U.S. Pat. No. 4,146,606, issued Mar. 27, 1979, 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.

U.S. Pat. No. 4,138,477, issued Feb. 6, 1979, discloses a composition to prevent and control mouth odor, 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. U.S. Pat. No. 4,396,599 issued Aug. 2, 1983, 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.

SUMMARY OF THE INVENTION

It is an object of this invention to provide improved oral hygiene compositions.

It is another object of this invention to provide oral hygiene compositions which prevent and control mouth odor, calculus, plaque, caries, and gingivitis.

It is a further object of this invention to provide oral hygiene compositions which minimize astringent taste and exhibit good fluoride and zinc ion bioavailability.

Other objects of this invention will be set forth in, or be apparent from the following detailed description of the invention.

The foregoing objects and other features and advantages of the present invention are achieved by oral hygiene compositions formulated to provide available fluoride and zinc ions from pharmaceutically acceptable salts in a formulation containing a specific buffering system and having a pH of from about 3.5 to 6.0.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to oral hygiene compositions containing an effective concentration of a pharmaceutically acceptable fluoride salt and a pharmaceutically acceptable zinc salt, a specific buffering agent and having a pH of from about 3.5 to 6.0.

Typical pharmaceutically acceptable fluoride compounds that are suitable for use in the compositions of this invention include sodium fluoride, potassium fluoride, lithium fluoride, aluminum fluoride, zinc fluoride, stannous fluoride, sodium monofluorophosphate, acidulated phosphate fluoride, ammonium fluoride, ammonium bifluoride, titanium tetrafluoride and amine fluoride.

Zinc salts that are suitable for use in the compositions of this invention include zinc chloride, zinc sulfate, zinc citrate, zinc acetate, zinc lactate, zinc salicylate, zinc thiocyanate, and, more generally, any pharmaceutically acceptable zinc salts.

The fluoride ion concentration can be from as low as 0.0025% to about 4.0% by weight. The preferred range of fluoride ion concentration is about 0.005% to about 1.0% by weight, more preferably about 0.01% to 0.5%. The zinc ion concentration should be from about 0.02% to 30.0% by weight, preferably from about 0.05% to 10.0% and more preferably from about 0.1% to 5.0%. 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

H45 150

sales
} Zn +
pharmaceutically
acceptable

or reducing the enamel solubility. The zinc ions help to prevent the formation of tartar, oral malodor 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. Sodium gluconate in an amount of from about 0.01 to 10.0%, preferably about 0.05 to 5.0% is a preferred buffering agent. Other organic acids/salts which can be utilized include maleic acid, aspartic acid, gluconic 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 same 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. Pat. No. 4,100,269 and the precipitated silica materials described in U.S. Pat. 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 dentifrice 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 cogenic mixture of conjugated polyoxybutylene-polyoxyethylene described in U.S. Pat. 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

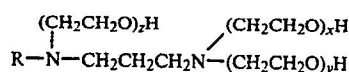
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the zinc chloride and can be present in the amount of from about 0.5 to 10%, preferably about 1.0 to 5.0%.

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 C₂M, 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 stearylammmonium 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 compatible 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 representative examples. It will be understood, however, that the invention is not confined to the specific limitations set forth in the indi-

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vidual examples but rather to the scope of the appended claims.

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 methyl cocoyl taurate	3.75
xanthan gum	1.00
hydroxyethylcellulose	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 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
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. 10.0 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
5	(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
10	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
15	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 fluoride	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
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ethanol	15.00
zinc chloride	0.50
sodium fluoride	0.05
sodium gluconate	0.27
saccharin	0.50
flavoring	1.00
propellant	5.00

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-continued

-continued

	% w/w
deionized water q.s. to	100.00

	% w/w
sodium fluoride	0.22
sodium gluconate	0.30
gum tragacanth	0.50
deionized water	3.00

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

What is claimed is:

1. An oral hygiene composition consisting essentially of an effective concentration of a pharmaceutically acceptable fluoride salt selected from the group consisting of sodium fluoride, potassium fluoride, lithium fluoride, aluminum fluoride, zinc fluoride, stannous fluoride, sodium monofluorophosphate, acidulated phosphate fluoride, ammonium fluoride, ammonium bifluoride, titanium tetrafluoride and amine fluoride, a pharmaceutically acceptable zinc salt selected from the group consisting of zinc chloride, zinc sulfate and zinc thiocyanate, a buffering agent selected from the group consisting of sodium gluconate, maleic acid, aspartic acid, gluconic acid, succinic acid, glucuronic acid, glucuronic acid lactone, fumaric acid and sodium glutamate and a suitable oral hygiene vehicle and having a pH of from about 3.5 to 6.0.
2. The composition of claim 1 wherein the fluoride ion is present in a concentration of from about 0.0025 to about 4.0% by weight.
3. The composition of claim 2 wherein the fluoride ion concentration is in the range of from about 0.005 to about 1.0 by weight.
4. The composition of claim 2 wherein the fluoride ion concentration is in the range of from about 0.02 to about 0.5% by weight.
5. The composition of claim 2 wherein the zinc ion is present in a concentration of from about 0.02 to about 30.0% by weight.
6. The composition of claim 5 wherein the zinc ion concentration is from about 0.05 to about 10.0% by weight.
7. The composition of claim 6 wherein the zinc ion concentration is from about 0.1 to about 5.0% by weight.
8. The composition of claim 1 wherein the buffering agent is present in a concentration of from about 0.01 to about 10.0% by weight.
9. The composition of claim 8 wherein the buffering agent concentration is from about 0.05 to about 5.0% by weight.
10. The composition of claim 1 wherein the buffering agent is sodium gluconate.
11. The composition of claim 1 wherein the vehicle comprises at least one member selected from the group consisting of glycerol, water, ethanol, polyethylene glycol, propylene glycol and sorbitol.

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 7/16, 7/26	A1	(11) International Publication Number: WO 97/40812 (43) International Publication Date: 6 November 1997 (06.11.97)
(21) International Application Number: PCT/US97/06758 (22) International Filing Date: 24 April 1997 (24.04.97) (30) Priority Data: 60/016,802 26 April 1996 (26.04.96) US (71) Applicant: WARNER-LAMBERT COMPANY [US/US]; 201 Tabor Road, Morris Plains, NJ 07950 (US). (72) Inventors: PARIKH, Rita, M.; 496 Tether Lane, Paramus, NJ 07652 (US). HARPER, David, Scott; 178 Sycamore Terrace, Glen Rock, NJ 07452 (US). (74) Agents: RYAN, M., Andrea; Warner-Lambert Company, 201 Tabor Road, Morris Plains, NJ 07950 (US) et al.		(81) Designated States: AL, AU, BA, BB, BG, BR, CA, CN, CZ, EE, GE, GH, HU, IL, IS, JP, KR, LC, LK, LR, LT, LV, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, TR, TT, UA, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: ENHANCED ZINC CONTAINING ORAL COMPOSITION (57) Abstract An improved oral composition, such as a toothpaste, gel dentifrice, toothpowder, tooth hardener, anticalculus composition, gum or lozenge, comprising a bacteriostatic and anticalculus effective amount of zinc ions and an antimicrobial effective amount of one or more essential oils is disclosed. The oral composition has longer-lasting breath freshening activity. The preferred source of zinc ion is zinc chloride. The preferred essential oils are thymol, menthol, eucalyptol and methyl salicylate.		

Summary of the Invention

It is an object of this invention to provide an improved oral composition with a bacteriostatic and anticalculus effective amount of zinc ion and an antimicrobial effective amount of one or more essential oils.

5 It is another object of this invention to provide an improved oral composition with longer lasting breath freshening activity.

It is another object of this invention to provide a method of making an improved oral composition containing a source of zinc ions and one or more essential oils.

10 It is another object of this invention to provide a method of using an improved oral composition containing a source of zinc ions and one or more essential oils.

Brief Description of the Drawing

Figure 1 is a graph of the bacteriostatic efficacy of zinc ion dentifrice compositions made with and without essential oils.

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Detailed Description

The oral composition of this invention comprises an anticalculus and bacteriostatic effective amount of zinc ion, an antimicrobial effective amount of one or more essential oils, and an orally acceptable vehicle or base. ←

20 The oral composition of this invention is preferably a dentifrice, such as toothpaste and gel. Other compositions may include mouthwashes, mouthrinses, tooth powders, tooth hardeners, antitartar compositions, anticalculus compositions, gums, tablets, lozenges, troches and the like. The base or the medium for the active components of the composition of this invention will be any which is conventionally employed and known to those skilled in the art.

25 The zinc ion in the composition of this invention may be provided by a number of zinc-containing compounds. The preferred source of zinc ion is one or more water-soluble zinc salts or zinc oxide. Suitable zinc salts include but are not limited to zinc sulphate, zinc chloride, zinc bromide, zinc iodide, zinc nitrate, and carboxylic acid salts of ←
30 zinc. The preferred zinc salt is zinc chloride. The dentifrice composition of this invention ←

is formulated to provide at least about 50 ppm of zinc ion; more preferably at least about 1500 ppm of zinc ion. The water-soluble zinc salt or salts are present in the composition of this invention in an amount of up to about 5% by weight of the composition (hereinafter "w/w"), preferably about 0.25 to about 3% w/w; and most preferably about 0.5 to about 2% w/w. In the case of a dentifrice composition 0.01% zinc chloride by weight provides about 50 ppm zinc ion; 0.2% zinc chloride by weight provides about 1000 ppm zinc ion; and 0.3% zinc chloride provides about 1500 ppm zinc ion. The preferred amount of zinc chloride in the dentifrice composition of this invention is, therefore, about 0.01% w/w; the more preferred amount of zinc chloride is about 0.2% w/w; and the most preferred amount is about 0.5% w/w.

Zinc ions can also be provided by suspensions of zinc oxide particles. The zinc oxide is present in the composition in an amount sufficient to provide at least about 50 ppm zinc ion; preferably at least about 1500 ppm zinc ion.

Essential oils are volatile aromatic oils that may be synthetic or may be derived from plants by distillation, expression or extraction, and that usually carry the odor or flavor of the plant from which they are obtained. Essential oils are widely used in oral care products. Some essential oils show long-lasting germicidal effectiveness against the most common pathogens in the mouth. These pathogens are frequently associated with oral malodor, plaque, and gingivitis. The essential oils in the composition of this invention include but are not limited to thymol, methyl salicylate, menthol, eucalyptol, camphor, anethole, carvone, eugenol, isoeugenol, liminene, osimen, n-decyl alcohol, citronel, alpha-salpineol, methyl acetate, chlorothymol, citronellyl acetate, methyl eugenol, cineol, ethyl linalaol, safrola vinillin, spearmint oil, peppermint oil, lemon oil, orange oil, sage oil, rosemary oil, cinnamon oil, pimento oil, laurel oil, cedarleaf oil, and clove oil. The preferred essential oils in the composition of this invention are thymol, methyl salicylate, menthol, and eucalyptol. The most preferred essential oil is thymol.

In a dentifrice composition of this invention it is desirable that there be at least about 0.075% by weight of each of such four essential oils; preferably at least about 0.125% by weight; and most preferably at least about 0.2% by weight of each essential oil.

artificial vanilla, cinnamon, various fruit flavors, both singly or mixed, and the like. The amount of flavoring agent employed herein is normally a matter of preference subject to such factors as the type of final dentifrice composition, the individual flavor employed, and the strength of flavor desired.

5 The coloring agents (colors, colorants) useful in the present invention are used in amounts effective to produce the desired color. These coloring agents include pigments which may be incorporated in amounts up to about 6%, by weight of the composition. A preferred pigment, titanium dioxide, may be incorporated in amounts up to about 2%, and preferably less than about 1%, by weight of the composition. A full recitation of all F.D.
10 & C colorants and their corresponding chemical structures may be found in the Kirk-Othmer Encyclopedia of Chemical Technology, 3rd Edition, in volume 5 at pages 857-884, which text is incorporated herein by reference.

 Suitable abrasives in the dentifrice include hydrated silica, calcium carbonate, calcium pyrophosphate, dicalcium phosphate dihydrate, or alkali metal meta-phosphates.
15 Silica abrasives in the dentifrice composition according to this invention may include among others, ZEODENT® (113), manufactured by J. M. Huber Corp. and SYLOID® or SYLODENT®, manufactured by W.R. Grace Co. These abrasives may be used in amounts up to about 75.0% w/w of the composition, preferably in amounts from about 5.0% w/w to about 40% w/w of the composition, and most preferably from about 7.0%
20 w/w to about 30.0% w/w of the composition.

Suitable buffers include citric acid-sodium citrate, acetic acid-sodium acetate,
sodium saccharine-acid saccharine, and benzoic acid and benzoate in amounts up to about 1%, and preferably from about 0.05% to about 0.5%, by weight of the composition. The
pH for the preferred embodiment of the dentifrice of the present invention is from 3.0 to
25 about 5.5.

 Suitable preservatives in this invention include benzoic acid, sodium benzoate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), ascorbic acid, methyl paraben, propyl paraben, tocopherols and mixtures thereof. Preservatives when used are generally present in amounts up to about 1.0% w/w, and preferably from about 0.1% w/w
30 to about 1.0% w/w of the dental gel composition.

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The present invention is further illustrated by the following examples which are, however, not included to limit the effective scope of the claims. All parts and percentages in the examples and throughout the specification and claims are by weight of the final composition unless otherwise specified. Although the invention is described with regard to the following illustrative examples, it will be apparent to one skilled in the art that various modifications may be made thereto which fall within its scope.

EXAMPLE 1

A mouthwash with the ability to prevent the creation of malodors for several hours was prepared by combining the following components in potable water.

	COMPONENTS	AMOUNT
	Ethanol	216 mls.
	Thymol	0.639 grams
15	Menthol	0.425 grams
	Methyl Salicylate	0.66 grams
	Eucalyptol	0.922 grams
	ZnCl ₂	1.0 grams
	Benzoic Acid	1.2 grams
20	Sodium Benzoate	0.35 grams
	Caramel	0.24 grams
	Poloxamer 407	2.0 grams
	Sorbitol	200 grams
	1-Propanol (Flavorant)	5.0 grams
25	Water	Q.S. to 1 Liter

The above composition was prepared by adding the essential oils (thymol, menthol, methyl salicylate and eucalptol), Poloxamer 407, benzoic acid, and 1-propanol to ethanol, followed by the addition of 250 ml of potable water.

To that mixture was added ZnCl₂. Sodium benzoate, zinc chloride, sorbitol, and caramel were then added; q.s. to 1000 ml with potable water.

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EXAMPLE 2

A dentifrice with zinc chloride and essential oils was formulated. Another component in the dentrifrice was hydroxyethylcellulose (Natrosol 250H.) Natrasol 250H in the dentifrice helps reduce the astringency caused by zinc ions.

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Ingredient	Percent	For 1kg
Water, purified	32.52930	325.2930
Sorbitol 70%	35.000	350.0000
Polyethylene glycol	2.000	20.0000
Sodium fluoride 1100ppm	0.2430	2.430
Na Saccharin NF 000A176	0.700	7.0000
Saccharin NF 000A176	0.500	5.0000
Zinc chloride	0.500	5.0000
Sodium benzoate	0.200	2.0000
FD+C Blue #1 .2%	1.000	10.0000
D&C Yellow #10 .1%	0.250	2.5000
Sylodent 753	25.0	250.0000
Titanium dioxide	0.350	3.5000
Natrosol 250H	0.75	7.5
CMC 7mf	1.1	11.0
Glycerin 95%	6.000	60.0000
* 17814-057-1 flavor (-17)	2.36670	23.6670
SLS	1.500	15.0000
SUB TOTAL	67.4707	674.7070
TOTAL	100.0000	1000.0000
TOTAL FLAVOR	2.3667	23.6670
	pH	Viscosity
* Includes: Thymol 0.5112%, Methyl salicylate 0.4800%, Menthol 0.3400%, and Eucalyptol 0.7376%		

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What is claimed is:

1. An improved oral composition comprising a bacteriostatic and anticalculus effective amount of zinc ion provided by one or more zinc-containing compounds and an antimicrobial effective amount of one or more essential oils.
2. The improved oral composition of claim 1 wherein said oral composition is a dentifrice.
3. The improved oral composition of claim 2 wherein the amount of zinc ion in said composition is at least about 50 ppm.
4. The improved oral composition of claim 3 wherein the amount of zinc ion in said composition is at least about 1500 ppm.
5. The improved oral composition of claim 2 wherein said one or more zinc-containing compounds are selected from the group comprising zinc salts and zinc oxide.
6. The improved oral composition of claim 5 wherein said one or more zinc salts are selected from the group comprising zinc chloride, zinc sulphate, zinc bromide, zinc iodide, zinc nitrate, and carboxylic acid salts of zinc.
7. The improved oral composition of claim 6 wherein said zinc salt is zinc chloride.
8. The improved oral composition of claim 6 wherein said one or more zinc salts are present in an amount of at least about 0.01% by weight of said composition.
9. The improved oral composition of claim 8 wherein said one or more zinc salts are present in an amount of at least about 0.2% by weight of said composition.
10. The improved oral composition of claim 9 wherein said one or more zinc salts are present in an amount of at least about 0.5% by weight of said composition.
11. The improved oral composition of claim 1 wherein said one or more essential oils are selected from the group comprising thymol, menthol, methyl salicylate, and eucalyptol.
12. The improved oral composition of claim 11 wherein said one or more essential oil is thymol.
13. The improved oral composition of claim 12 wherein the concentration by weight of thymol is in an amount of from about 0.01% w/w to about 1.0% w/w; the concentration by weight of menthol is from about 0.01% w/w to about 1.0% w/w; the

concentration by weight of eucalyptol is from about 0.01% w/w to about 1.0% w/w; and the concentration of methyl salicylate is from about 0.01% w/w to about 1.0% w/w.

14. The improved oral composition of claim 1 wherein said oral composition is a mouthwash.

15. A method for preparing an improved dentifrice comprising a bacteriostatic and anticalculus effective amount of zinc ion provided by one or more zinc-containing compounds and an antimicrobial effective amount of one or more essential oils comprising:

- a) combining water, a source of zinc ion, one or more humectant, sweeteners, buffers and preservatives;
- b) admixing one or more humectant with gum to form a second mixture;
- c) admixing said first and second mixture to form a third mixture;
- d) admixing titanium dioxide and silicas to form a fourth mixture;
- e) admixing said third and fourth mixtures to form a fifth mixture
- f) admixing said fifth mixture with colors, essential oils, flavors, and surfactants to form a sixth mixture;
- g) adjusting the pH of said sixth mixture to a pH of about 3.0 to about 5.5 with acidifiers;
- h) deaerating said sixth mixture under a vacuum.

16. A method of reducing oral malodor by using an improved oral composition comprising a bacteriostatic and anticalculus effective amount of zinc ion provided by one or more zinc-containing compounds and an antimicrobial effective amount of one or more essential oils.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIVISION DE NUEVAS CREACIONES

2020

Bogotá, D.C., Abril 5 de 2005

Doctor

CARLOS ORLANDO MAYA RODRÍGUEZ

ASUNTO	Radicación No.	00 025 234
	Trámite	002
	Evento	001
	Actuación	430
	Oficio No.	12826
	Folios	0

Como resultado del examen de patentabilidad de la solicitud de patente de invención, realizado según lo establece el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se notifica el siguiente concepto técnico:

1. Documentos estudiados

Para el presente estudio se tuvieron en cuenta el capítulo descriptivo comprendido en los folios 2 - 29 y el capítulo reivindicatorio de los folios 30 - 31 de la solicitud en estudio.

2. Objeto de la Invención

El objeto de la presente solicitud de patente de invención consiste en:

Las reivindicaciones 1 - 6 se refieren a una composición dentífrica que contiene un compuesto de Zinc (citrato, óxido, pirofosfato ó silicato), un tampón (ácido cítrico-citrato sódico, ácido fosfórico-fosfato sódico, mono ó disódico, ácido acético-acetato sódico, ácido succínico-succinato sódico, ácido aconítico-aconitato sódico ó ácido benzoico-benzoato sódico) que mantiene el pH entre 3.0 - 5.5 y un vehículo oral.

El problema planteado en esta solicitud es la necesidad de proporcionar una composición dentífrica que contiene Zinc, con buena biodisponibilidad y una proporción baja.

Para resolver este problema técnico la solicitud en estudio proporciona una composición dentífrica que contiene un compuesto de Zinc, un tampón que mantiene el pH entre 3.0 - 5.5 y un vehículo oral.

El objeto de la invención definido anteriormente se clasificó de acuerdo con la IPC: A 61 K 7/16.

También se reivindica prioridad de la Solicitud de Patente de los Estados

Unidos US 09 288 828 de abril 8 de 1999, con respecto a la cual la fecha de presentación de la actual solicitud cumple el plazo máximo permitido.

3. Determinación del Estado de la Técnica

El artículo 16 de la decisión 486 de la comisión de la Comunidad Andina que establece que *"El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización, comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente o, en su caso, de la prioridad reconocida."*

Solo para el efecto de la determinación de la novedad, también se considerará dentro del estado de la técnica, el contenido de una solicitud de patente en trámite ante la oficina nacional competente, cuya fecha de presentación o de prioridad fuese anterior a la fecha de presentación o de prioridad de la solicitud de patente que se estuviese examinando, siempre que dicho contenido esté incluido en la solicitud de fecha anterior cuando ella se publique o hubiese transcurrido el plazo previsto en el artículo 40".

Considerando que la fecha de presentación de la primera solicitud de patente de la cual se reivindica prioridad es abril 8 de 1999, se consultaron las bases de datos y los archivos con que cuenta la entidad con fecha de publicación anterior y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

No.	Documento	Título	Fecha de Publicación
D1	US 4 568 540	Composiciones de Higiene oral	Feb 4, 1986
D2	WO 97 40812	Composición oral que contiene Zinc mejorado	Nov 6, 1997

4. Evaluación de los requisitos de Patentabilidad

El artículo 14 de la Decisión 486 de la Comisión de la Comunidad Andina establece que *"Los Países Miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial"*.

En cumplimiento del artículo 14 de la Decisión 486, se procedió a evaluar el cumplimiento de los requisitos de novedad, nivel inventivo y aplicación industrial, con el fin de establecer la patentabilidad de la invención reivindicada en la solicitud en estudio.

Evaluación de la Novedad

El Art. 16 de la Decisión 486 de la Comisión de la Comunidad Andina establece: *"Una invención se considerará nueva cuando no está comprendida en el estado de la técnica. El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente, o, en su caso, de la prioridad reconocida."*

Solo para el efecto de la determinación de la novedad, también se considerará dentro del estado de la técnica, el contenido de una solicitud de patente en trámite ante la oficina nacional competente, cuya fecha de presentación o de

prioridad fuese anterior a la fecha de presentación o de prioridad de la solicitud de patente que se estuviese examinando, siempre que dicho contenido esté incluido en la solicitud de fecha anterior cuando ella se publique o hubiese transcurrido el plazo previsto en el Art 40".

Las reivindicaciones 1 - 6 se refieren a una composición dentífrica que contiene un compuesto de Zinc (citrato, etc. óxido, pirofosfato ó silicato), un tampón (ácido cítrico-citrato sódico, ácido fosfórico-fosfato sódico, mono ó disódico, ácido acético-acetato sódico, ácido succínico-succinato sódico, ácido aconítico-aconitato sódico ó ácido benzóico-benzoato sódico) que mantiene el pH entre 3.0 - 5.5 y un vehículo oral.

D1 enseña una composición dentífrica que contiene un compuesto de Zinc (citrato y sales de Zinc farmacéuticamente aceptables, según columna 2, renglones 46 a 51, folio 145), un tampón (ácido succínico-succinato sódico, u otros de ácidos apropiados) que mantiene el pH entre 3.5 - 6.0 y un vehículo oral.

D2 enseña una composición dentífrica que contiene un compuesto de Zinc (óxido, sales de Zinc de ácidos carboxílicos, según página 3, renglones 26 - 30, folio 151), un tampón (ácido cítrico-citrato sódico, ácido acético-acetato sódico, ó ácido benzóico-benzoato sódico) que mantiene el pH entre 3.0 - 5.5 y un vehículo oral.

Se observa que las reivindicaciones 1 a 6 enseñan una composición dentífrica que contiene un compuesto de Zinc, un tampón que mantiene el pH entre 3.0 - 5.5 y un vehículo oral, de la misma manera que las anterioridades D1 que enseña una composición dentífrica que contiene un compuesto de Zinc, un tampón que mantiene el pH entre 3.0 - 5.5 y un vehículo oral y D2 enseña una composición dentífrica que contiene un compuesto de Zinc, un tampón que mantiene el pH entre 3.0 - 5.5 y un vehículo oral. Puesto que los tres elementos: un compuesto de Zinc, un tampón que mantiene el pH entre 3.0 - 5.5 y un vehículo oral que se mencionan en estas reivindicaciones ya habían sido considerados en estas anterioridades, es claro que estas composiciones no son nuevas.

Evaluación del Nivel Inventivo

El artículo 18 de la Decisión 486 de la Comisión de la Comunidad Andina establece que *Se considerará que una invención tiene nivel inventivo, si para una persona del oficio normalmente versada en la materia técnica correspondiente, esa invención no hubiese resultado obvia ni se hubiese derivado de manera evidente del estado de la técnica.*

Las reivindicaciones 1 - 6 se refieren a una composición dentífrica que contiene un compuesto de Zinc (citrato, etc. óxido, pirofosfato ó silicato), un tampón (ácido cítrico-citrato sódico, ácido fosfórico-fosfato sódico, mono ó disódico, ácido acético-acetato sódico, ácido succínico-succinato sódico, ácido aconítico-aconitato sódico ó ácido benzóico-benzoato sódico) que mantiene el pH entre 3.0 - 5.5 y un vehículo oral.

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oral.

D2 enseña una composición dentífrica que contiene un compuesto de Zinc (óxido, sales de Zinc de ácidos carboxílicos, según página 3, renglones 26 - 30, folio 151), un tampón (ácido cítrico-citrato sódico, ácido acético-acetato sódico, ó ácido benzóico-benzoato sódico) que mantiene el pH entre 3.0 - 5.5 y un vehículo oral.

Se observa que la combinación de las enseñanzas de estas anterioridades: D1 que enseña una composición dentífrica que contiene un compuesto de Zinc (citrato y sales de Zinc farmacéuticamente aceptables, según columna 2, renglones 46 a 51, folio 145), un tampón (ácido succínico-succinato sódico, u otros de ácidos apropiados) que mantiene el pH entre 3.5 - 6.0 y un vehículo oral y D2 que enseña una composición dentífrica que contiene un compuesto de Zinc (óxido, sales de Zinc de ácidos carboxílicos, según página 3, renglones 26 - 30, folio 151), un tampón (ácido cítrico-citrato sódico, ácido acético-acetato sódico, ó ácido benzóico-benzoato sódico) que mantiene el pH entre 3.0 - 5.5 y un vehículo oral; sugiere la composición dentífrica que contiene un compuesto de Zinc, un tampón que mantiene el pH entre 3.0 - 5.5 y un vehículo oral de las reivindicaciones 1 a 6, que es objeto de esta solicitud. Las reivindicaciones no mencionan una característica que conceda un efecto diferente o especial a la composición, así que esta es obvia y evidente para una persona versada en la materia. Entonces debido a que: (a) la conformación de las composiciones de esta solicitud, a partir de las anterioridades, es evidente para una persona conocedora de la materia; porque siendo bien conocidas las composiciones dentífricas que contienen un compuesto de Zinc, un tampón que mantiene el pH entre 3.0 - 5.5 y un vehículo oral, para una persona conocedora de la materia era evidente el elaborar las composiciones de esta solicitud de manera similar, teniendo en cuenta estos compuestos; (b) las reivindicaciones de esta solicitud no mencionan una característica que conceda un efecto diferente o especial a las composiciones, que pueda considerarse como un aporte a la técnica, porque las anterioridades ya enseñaban los compuestos de zinc, los tampones, los vehículos orales, las composiciones dentífricas elaboradas con estos y las condiciones de pH entre 3.0 - 5.5 requeridas por estas, así que estas son obvias para una persona versada en la materia y (c) el problema planteado en esta solicitud era la necesidad de proporcionar una composición dentífrica que contiene Zinc, con buena biodisponibilidad y una proporción baja y puesto que para resolver este problema técnico la solicitud proporciona una composición dentífrica que contiene un compuesto de Zinc, un tampón que mantiene el pH entre 3.0 - 5.5 y un vehículo oral, es decir de manera similar a como se resolvía en las anterioridades D1 y D2; entonces esta solicitud no tiene **nivel inventivo**. La reivindicación 1 menciona que la biodisponibilidad del Zinc es mínimo de 1000 ppm, pero esto ya se obtenía en las composiciones conocidas, como se observa en la tabla 2 (folio 26) según la cual el Zinc biodisponible del ejemplo comparativo es de 1550. De manera que no hay nivel inventivo.

5. Conclusión

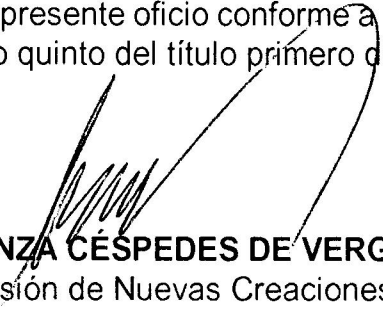
En conclusión, los requisitos de patentabilidad de la presente solicitud están afectados así:

Item	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	US 4 568 540	1 a 6	Novedad y Nivel inventivo
D2	WO 97 40812	1 a 6	Novedad y Nivel inventivo

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En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de la notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Unica No. 10 de 2001.


ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe de la División de Nuevas Creaciones.

El anterior requerimiento fue notificado por fijación en lista, de fecha
21 ABR. 2005.

CONCEPTO TÉCNICO No. 506	EXAMINADOR TÉCNICO Código 202007
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