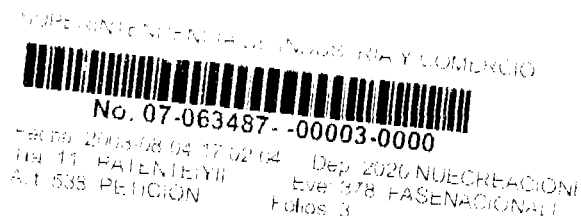


AS. 104.421



Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIVISION DE NUEVAS CREACIONES

E. S. D.

REF.: Expediente No. 07 063.487 - Solicitud de Patente FASE NACIONAL

Corresp. a la Solicitud Internacional PCT/US2005/046242.

a nombre de: **COLGATE-PALMOLIVE COMPANY.**

Titulada: COMPOSICIÓN DE CUIDADO BUCAL QUE CONTIENE EXTRACTO DE
CAMELLIA NO OXIDADO.

JUAN PABLO CADENA SARMIENTO, vecino de Bogotá, portador de la tarjeta profesional No. 57492 del Consejo Superior de la Judicatura, obrando como apoderado de la Sociedad **COLGATE-PALMOLIVE COMPANY**, según lo acredita el documento de poder presentado en esa División, de acuerdo con el Artículo 44 de la Decisión 486 de la Comisión de la Comunidad Andina, me permito solicitar que se examine si la invención contenida en la solicitud en referencia es patentable.

De acuerdo con lo anterior, me permito anexar los recibos oficiales de caja No. 08-48,480 y 08-48,481 por valor de \$420.000.

De la Señora Jefe atentamente,

JUAN PABLO CADENA SARMIENTO

C.C. No. 80.410.337 de Usaquén

T.P. No. 57492 del C.S.J.

Cra 7 No. 71-21 Torre B, Piso 4

Bogotá, 04 de agosto de 2008

MEV/CAG/jpg

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 08 - 48,480
 FECHA : JUNIO 17 DE 2008

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 07-063487- -00003-0000

Fecha: 2008-06-04 17:02:04 Dep: 2020 NUECREACION
 Id: 11 PATENTABILIDAD Eje: 378 FASE NACIONAL
 Act: 5.55 PETICION Folios: 3

**** CONSIGNACION ****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
BRIGARD & CASTRO LTDA	CONSIGNACION	BANCO DE BOGOTA	062754387	3249606	16/06/2008	28,020,000.00

**** CONCEPTO ****

CANT. RENTISTED	CONCEPTO	TOTAL CONCEPTO
1 50005-01-01 SOLICITUDES	114 PTC CAP-II EXAMEN DE PATENTIBILIDAD	210,000.00
	TOTAL :	\$ 210,000.00

SON: DOSCIENTOS DIEZ MIL PESOS

RESPONSABLE :

RECIBO DE CAJA APLICADO AL EXPEDIENTE No.

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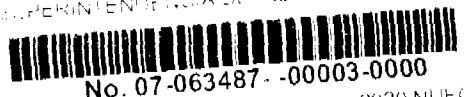
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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 900176089-2

RECIBO OFICIAL DE CAJA : 08 - 48.481
FECHA : JUNIO 17 DE 2008

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Tipo: 11 PATENTE(YO) Eje: 378 FASENACIONAL
Act: 334 PETICION Folios: 3

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	Vr. PAGO
BRIGARD & CASTRO LTDA	CONSIGNACION	BANCO DE BOGOTA	062754387	3249606	16/06/2008	28,020,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
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		TOTAL :	\$ 210,000.00

SON: DOSCIENTOS DIEZ MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 07-63487

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCION**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **589** DE

FECHA **29 DE FEBRERO DE 2008** EL TÉRMINO HÁBIL SEÑALADO POR LA

LEY EXPIRA EL **03 DE JUNIO DE 2008**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____

NO X

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- (71) Applicant (for all designated States except US): **THE PROCTER & GAMBLE COMPANY** [US/US]; One Procter & Gamble Plaza, Cincinnati, OH 45202 (US).
- (72) Inventors: and
- (75) Inventors/Applicants (for US only): **ZHU, Long** [CN/CN]; Beijing Post & Telecommunication University Beijing, g, Young Teacher Building 2, Room 212, Beijing 100876 (CN). **Ji, Ning** [CN/CN]; 6/7 floor Tongfang Building, Haidian District 100084 (CN).
- (74) Agents: **REED, T., David et al.**; The Procter & Gamble Company, 5299 Spring Grove Avenue, Cincinnati, OH 45217-1087 (US).
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WO 01/17494 A1

(54) Title: ORAL COMPOSITIONS COMPRISING TEA POLYPHENOL

(57) Abstract: Disclosed are oral compositions comprising: an effective amount of tea polyphenol; an effective amount of a buffering agent; from about 40 % to about 99 % of one or more aqueous carriers; wherein the oral composition has a total water content of from about 5 % to about 20 %.

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The term "dispenser", as used herein, means any pump, tube, or container suitable for dispensing toothpaste.

The term "oral composition" as used herein means the total composition that is delivered to the oral surfaces. The oral composition is a product, which in the ordinary course of usage, is not intentionally swallowed for purposes of systemic administration of particular therapeutic agents, but is rather retained in the oral cavity for a time sufficient to contact substantially all of the dental surfaces and/or oral tissues for purposes of oral activity. The oral compositions of the present invention are of course intended for human use, but they can equally advantageously be used for animals, such as household pets.

The term "aqueous carrier" as used herein means any safe and effective materials for use in the compositions of the present invention. Such materials include abrasive polishing materials, peroxide sources, alkali metal bicarbonate sources, anti-tartar agents, thickening materials, humectants, water, surfactants, titanium dioxide, antioxidants, metal ions, zinc phytic acid, coloring agents, flavor systems, xylitol, sweetening agents, herbal agents, anti-microbial agents, and mixtures thereof.

The present compositions comprise essential components, as well as optional components. The essential and optional components of the compositions of the present invention are described in the following paragraphs.

Tea Polyphenol

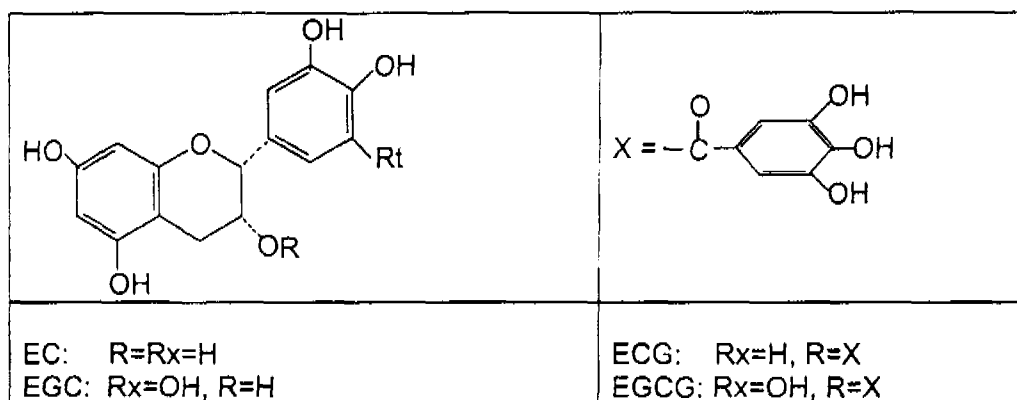
The compositions of the present invention include an effective amount of tea polyphenol. Tea polyphenol generally comprises about 20% to about 40% dry weight of tea, and thus is a major component of tea (*camellia sinensis* L), which is commonly drunk on a daily basis by many people throughout the world. Other components found in tea include lipopolysaccharide, caffeine, alkaloid, inorganic element, amino acid, organic acid, vitamin, protein, and other trace elements.

Tea polyphenol is a mixture of the polyphenolic species extracted from tea, the most important components of which are catechines, flavanols, flavanones, chlorogenic acid, phenolic acid, glycosids and their aglycons of plant pigment. Without being bound by theory, it is believed that the catechines are the component of the tea polyphenol that provides the physiologically efficacious effects. The other components of tea polyphenol are believed to improve the

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efficacy of the catechines, as well as to independently provide efficacious effects such as anti-bacteria effect and acceleration of saliva circulation.

The catechines include catechin, epicatechin (EC), epigallocatechin (EGC), epicatechin gallate (ECG), galocatechin gallate, and epigallocatechin gallate (EGCG). The chemical structures of these catechines are:



It is believed that the catechines are useful for anti-bacterial and breath protection effects. As the major components of malodor, methyl mercaptan and trimethylamine can be cleaned by using 2-5 mg/ml of catechines in about 2-5 minutes. At the same time, catechines can be adhered to the oral cavity for more than one hour. Without being bound by theory, it is also believed that tea polyphenol is potentially useful for anti-caries, anti-gingivitis, anti-stomatitis effect, as well as other oral health benefits.

Tea polyphenol is safe for humans. As noted above, it is a natural component of the teas that are regularly consumed by humans. Although it is believed that there is no true upper limit to amount of tea polyphenol that can be incorporated into the compositions of the present invention, it is believed that levels of from about 0.5% to about 2% as an active ingredient are sufficient to deliver its efficacious effects.

Without being bound by theory, it is believed that tea polyphenol can deliver breath protection benefit due to its ability to inhibit the certain bacteria, e.g., *S. mutans* and *S. sobrinud*, when present in low concentration, as well as its ability to kill such bacteria when present in high concentration. It is further believed that tea polyphenol can inhibit the reactivity of glycosyltransferase, which can catalyze sucrose to form water insoluble glucan. At this point the oral plaque formation can be stopped.

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compound which may be aliphatic or alkyl-aromatic in nature. Examples of suitable nonionic surfactants include poloxamers (sold under trade name Pluronic), polyoxyethylene, polyoxyethylene sorbitan esters (sold under trade name Tweens), fatty alcohol ethoxylates, polyethylene oxide condensates of alkyl phenols, products derived from the condensation of ethylene oxide with the reaction product of propylene oxide and ethylene diamine, ethylene oxide condensates of aliphatic alcohols, long chain tertiary amine oxides, long chain tertiary phosphine oxides, long chain dialkyl sulfoxides, and mixtures of such materials. The amphoteric surfactants useful in the present invention can be broadly described as derivatives of aliphatic secondary and tertiary amines in which the aliphatic radical can be a straight chain or branched and wherein one of the aliphatic substituents contains from about 8 to about 18 carbon atoms and one contains an anionic water-solubilizing group, e.g., carboxylate, sulfonate, sulfate, phosphate, or phosphonate. Other suitable amphoteric surfactants are betaines, specifically cocamidopropyl betaine. Mixtures of amphoteric surfactants can also be employed. Many of these suitable nonionic and amphoteric surfactants are disclosed by Gieske et al., U.S. Patent 4,051,234, issued September 27, 1977. The present composition typically comprises one or more surfactants each at a level of from about 0.25% to about 12%, preferably from about 0.5% to about 8%, and most preferably from about 1% to about 6%, by weight of the composition.

Titanium dioxide may also be added to the present composition. Titanium dioxide is a white powder which adds opacity to the compositions. Titanium dioxide generally comprises from about 0.25% to about 5%, by weight of the composition.

Antioxidants are generally recognized as useful in compositions such as those of the present invention and may be included herein. Antioxidants are disclosed in texts such as Cadenas and Packer, The Handbook of Antioxidants, © 1996 by Marcel Dekker, Inc. Antioxidants that may be included in the oral care composition or substance of the present invention include, but are not limited to Vitamin E, ascorbic acid (vitamin C), Uric acid, carotenoids, Vitamin A, flavonoids, herbal antioxidants, melatonin, aminoindoles, lipoic acids and mixtures thereof. Vitamins E and C are preferred, with levels of from about 0.01% to about 0.10% being desirable, and about 0.01% to about 0.05% being

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Alternatively, if xylitol is used as a sweetener, it may be present at a lower level, such as from about 0.005% to about 5%, by weight of the dentifrice composition.

Sweetening agents can be added to the compositions. These include saccharin, dextrose, sucrose, lactose, maltose, levulose, aspartame, sodium
5 cyclamate, D-tryptophan, dihydrochalcones, acesulfame, and mixtures thereof. Various coloring agents may also be incorporated in the present invention. Sweetening agents and coloring agents are generally used in toothpastes at levels of from about 0.005% to about 5%, by weight of the composition.

Herbal agents, including but not limited to, golden thread extract and
10 honeysuckle extract, may also be present in the compositions herein at levels of from about 0.01% to about 0.05%. Such herbal agents are believed to provide anti-bacteria efficacy.

Other anti-microbial agents can also be present in the oral care compositions or substances of the present invention. A preferable agent is 5-chloro-2-(2,4-dichlorophenoxy)-phenol, commonly referred to as triclosan, and
15 described in The Merck Index, 11th ed. (1989), pp. 1529 (entry no. 9573) in U.S. Patent No. 3,506,720, and in European Patent Application No. 0,251,591 of Beecham Group, PLC, published January 7, 1988. Without being bound by theory, it is believed that the combination of triclosan and tea polyphenol may
20 provides even better breath protection effect than tea polyphenol alone. Other specific antimicrobial agents include chlorhexidine, triclosan monophosphate, and essential oils including thymol, geraniol, carvacrol, citral, hinokitol, eucalyptol, and mixtures thereof. Triclosan and other agents of this type are disclosed in Parran, Jr. et al., U.S. Patent 5,015,466, issued May 14, 1991, and
25 U.S. Patent 4,894,220, Jan. 16, 1990 to Nabi et al. These agents may be present at levels of from about 0.01% to about 1.5%, by weight of the composition.

Also included among such other anti-microbial agents are water insoluble non-cationic antimicrobial agents such as halogenated diphenyl ethers, phenolic compounds including phenol and its homologs, mono and poly-alkyl and
30 aromatic halophenols, resorcinol and its derivatives, bisphenolic compounds and halogenated salicylanilides, benzoic esters, and halogenated carbanilides. The water soluble antimicrobials include quaternary ammonium salts and bis-biquanide salts, among others. Triclosan monophosphate is also a suitable water soluble antimicrobial agent. The quaternary ammonium agents include
35 those in which one or two of the substitutes on the quaternary nitrogen has a

comprises contacting the dental enamel, tongue, and other surfaces of the oral cavity or the mouth of a human or an animal with the oral compositions according to the present invention.

Examples & Method of Manufacturing

- 5 The following examples further describe and demonstrate embodiments within the scope of the present invention. These examples are given solely for the purpose of illustration and are not to be construed as limitations of the present invention as many variations thereof are possible without departing from the spirit and scope.

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Component	Ex. 1	Ex. 2	Ex. 3	Ex. 4	Ex.5
Tea Extract ¹	2.000	2.000	0.500	0.500	2.000
Sodium Fluoride, USP	0.321	0.321	0.321	0.310	0.321
Sorbitol Solution, USP	27.916	27.916	30.000	-	27.916
Precipitated Silica Abrasive	20.000	20.000	20.000	-	20.000
Treated Water	16.000	16.000	16.000	10.000	16.000
Triclosan, USP	0.280	0.280	0.280	0.280	0.280
Carbomer 956	0.250	0.250	0.250	-	0.250
Saccharin, Sodium, USP	0.370	0.370	0.370	0.250	0.370
Xanthan Gum	0.900	0.900	0.900	0.200	0.900
Tetrasodium Pyrophosphate	1.908	0.740	-	-	0.740
Tetrapotassium Pyrophosphate	3.159	1.985	-	-	1.985
Golden Thread Extract	0.010	0.010	0.010	-	0.010
Glycerin, USP	7.000	7.000	8.600	12.000	7.000
Sodium Alkyl Sulfate Solution (27.9%)	7.500	7.500	7.500	-	7.500
Polyethylene Glycol-300	6.000	6.000	6.000	5.000	6.000
Flavor	1.000	1.000	1.000	1.000	1.000
Sodium Acid Pyrophosphate	1.344	3.500	-	-	3.500
FD&C Blue Dye 1	0.0015	0.0015	0.0015	-	0.0015
FD&C Yellow # 5	0.0005	0.0005	0.0005	-	0.0005
Honeysuckle Extract	0.040	0.040	0.040	-	0.040
Titanium Dioxide, Rutile, USPUA 970	4.000	4.000	-	-	3.94

Sodium-citrate monohydrate	-	-	4.000	-	-
Acid-citrate dihydrate	-	-	0.235	-	-
Titanium Dioxide	-	-	4.000	-	-
Trisodium Phosphate, Dodecahydrate	-	-	-	0.100	-
Monosodium Phosphate	-	-	-	1.500	-
Blue lake dispersion GB ²	-	-	-	0.360	-
Carboxymethylcellulose, Sodium, 9M31XF	-	-	-	1.000	-
Silica, Dental Type, NF (8% LOD) Z119	-	-	-	20.000	-
Sodium Lauryl Sulfate Solution	-	-	-	7.500	-
Sorbitol, 70% Solution	-	-	-	40.000	-
Vitamin C	-	-	-	-	0.05
Vitamin E	-	-	-	-	0.01
pH	8	5.8	5.8	5.6	5.8

¹ e.g., Hangzhou tea

² Available from the Warner Jenkinson Company

Component	Ex. 6	Ex. 7	Ex. 8	Ex. 9
Sodium Fluoride, USP	0.310	-	-	-
Treated Water	10.000	7.000	7.000	7.000
Triclosan, USP	0.280	-	-	-
Xanthan Gum	0.200	0.200	0.200	0.200
Glycerin, USP	12.000	23.40	42.440	29.94
Sodium Alkyl Sulphate Solution (27.9%)	7.500	4.000	4.000	4.000
Polyethylene Glycol-300	5.000	3.000	3.000	3.000
Flavor	1.000	1.000	1.000	1.000
Tea Extract ¹	0.500	2.0	1.0	1.5
Trisodium Phosphate, Dodecahydrate	0.100	-	-	-
Monosodium Phosphate	1.500	-	-	-
Carboxymethylcellulose, Sodium, 9M31XF	-	0.600	0.600	0.600
Silica, Dental Type, NF (8% LOD) Z119	20.000	22.000	19.00	22.000

WHAT IS CLAIMED IS:

1. An oral composition comprising:
 - a. an effective amount of tea polyphenol;
 - b. an effective amount of a buffering agent;
 - c. from about 40% to about 99% of one or more aqueous carriers;5 wherein the oral composition has a total water content of from about 5% to about 20%.
2. The composition of Claim 1 further comprising from about 0.15% to about 2.5% of a fluoride ion source.
3. The oral composition according to Claim 1 comprising from about 0.5% to about 2% of tea polyphenol.
4. The oral composition according to Claim 1 wherein the buffering agent is selected from the group consisting of pyrophosphate salts, citric acid, sodium citrate, and mixtures thereof.
5. The oral composition of Claim 1 wherein the aqueous carriers are materials selected from the group consisting of abrasive polishing materials, peroxide sources, alkali metal bicarbonate sources, anti-tartar agents, thickening materials, humectants, water, surfactants, titanium dioxide, antioxidants, metal ions, zinc phytic acid, coloring agents, flavor systems, xylitol, sweetening agents, 5 herbal agents, anti-microbial agents, and mixtures thereof.
6. The oral composition according to Claim 5 wherein the anti-microbial agent is triclosan.
7. The oral composition according to Claim 6 wherein the abrasive polishing material is selected from the group consisting of silicas, aluminas, phosphates, orthophosphates, polymetaphosphates, and mixtures thereof.
8. The oral composition according to Claim 1 wherein the composition has a pH of from about 4 to about 8.



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- » Why isn't the abstract available for XP documents?

COMPOSITION FOR ORAL PURPOSES

Bibliographic data

[Original document](#)

[INPADOC legal status](#)

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Also published as:

Publication date: 1986-09-01

[JP6035376 \(B\)](#)

Inventor(s): HAYASHI HIROYUKI; YAMAMOTO YOICHI +

[JP1909778 \(C\)](#)

Applicant(s): SUNSTAR INC +

Classification:

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- European: **A61K8/49F; A61K8/49F1; A61K8/97; A61Q11/00**

Application number: JP19850039538 19850227

Priority number(s): JP19850039538 19850227

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Abstract of JP 61197510 (A)

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PURPOSE A composition that contains small amounts of a nitroimidazole derivative and a specific compound, thus being used for prevention of periodontal diseases and stomatitis. A disease, it causes no side effects, even when it is given continuously, inhibits gram-negative anaerobic microorganisms from forming volatile sulfur compounds in oral cavity.

CONSTITUTION The objective composition contains a nitroimidazole derivative such as metronidazole and extracts from leaves of camellia plant such as tea tree or camellia or sodium copper chlorophyllin. The amount of sodium copper chlorophyllin, or the tea-leaf extract is 0.001-1.0wt% based on the composition, while the amount of the nitroimidazole derivative is 0.0001-0.1wt%. The resultant composition is used in the form of tooth paste, tooth powder, mouth wash, gingiva massage cream or tooth-aid or paste part. The volatile sulfur compounds are, e.g., hydrogen sulfide, methyl mercaptan, etc.

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(19) 世界知的所有権機関
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2003年11月20日 (20.11.2003)

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(MAEDA, Mitsuru) [JP-JP]: 〒520-0244 滋賀県 大津市 衣川 2-1 5-5 Shiga (JP).

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(84) 指定国/広域: ヨーロッパ特許 (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR).

(71) 出願人/米国を除く全ての指定国について: サントリー株式会社 (SUNTORY LIMITED) [JP-JP]: 〒530-8203 大阪府大阪市北区堂島浜2丁目1番40号 Osaka (JP).

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(72) 発明者: および

(75) 発明者/出願人/米国についてののみ: 前田 満

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(54) Title: GALLOCATECHIN GALLATE-CONTAINING COMPOSITION

(54) 発明の名称: ガロカテキンガレート含有組成物

(57) Abstract: It is intended to provide a safe and highly efficacious antibacterial composition which is to be used in products mainly taken into the human or animal body or employed in the oral cavity such as foods and oral hygienic preparations without damaging the tastes of foods and drinks. The above composition contains gallocatechin gallate as a potentiator for antibacterial catechins. In particular, the antibacterial effects of the antibacterial catechins on bacteria causative of human decay such as *Streptococcus mutans* are enhanced thereby. The composition can be produced by mixing antibacterial catechins with gallocatechin gallate. Alternatively, it can be produced as a composition containing as the main component an adsorption fraction which is obtained by subjecting a solvent extract of tea leaves to adsorption by a synthetic adsorbent selected from among aromatic synthetic adsorbents and methacrylic synthetic adsorbents.

(57) 要約: 本発明は、食品および口腔衛生剤などの、主としてヒトや動物の体内に摂取されまたは口腔内で使用される製品に使用する、飲食物の味を損なうことなく、安全で、効果の高い抗菌組成物を提供する。本発明の組成物は、ガロカテキンガレートを抗菌性カテキン類の作用増強剤として含有し、特にストレプトコッカス・ミュータンス等の虫歯菌に対して、抗菌性カテキン類の抗菌性が増強されている。本発明の組成物は、抗菌性カテキン類とガロカテキンガレートを混合して製造することができ、あるいは茶葉の溶媒抽出物を芳香族系合成吸着剤またはメタクリル系合成吸着剤から選ばれた合成吸着剤を用いる吸着処理に付して得られる合成吸着剤吸着成分を主成分とする組成物として製造することもできる。

WO 03/094878 A1



US 2006/0134286A1

(19) **United States**(12) **Patent Application Publication****Maeda**(10) **Pub. No.: US 2006/0134286 A1**(43) **Pub. Date: Jun. 22, 2006**(54) **GALLOCATECHIN GALLATE-CONTAINING COMPOSITION**(52) **U.S. Cl. 426/335**(75) **Inventor: Mitsuru Maeda, Shiga (JP)**(57) **ABSTRACT**

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MATHIS)****POST OFFICE BOX 1404****ALEXANDRIA, VA 22313-1404 (US)**(73) **Assignee: Suntory Limited, Osaka-shi, Osaka (JP)**(21) **Appl. No.: 10/513,914**(22) **PCT Filed: May 12, 2003**(86) **PCT No.: PCT/JP03/05884**(30) **Foreign Application Priority Data**

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Publication Classification(51) **Int. Cl.****A23L 3/3463 (2006.01)**

The present invention provides a safe and highly effective antibacterial composition without impairing the flavor of foods or drinks, which composition is used in products such as foods and oral care goods which are mainly to be taken into human or animal bodies or mainly to be used in the oral cavity.

The composition according to the present invention contains gallocatechin gallate as an agent for enhancing the activity of antibacterial catechins in which the antibacterial activity of the antibacterial catechins against *Streptococcus mutans* is particularly enhanced. The composition according to the present invention can be produced by mixing the antibacterial catechins with gallocatechin gallate. Alternatively, it can be produced as a composition comprising a synthetic adsorbent-adsorbed fraction as the main component, which is obtained by subjecting a solvent-extract from tea leaves to an adsorption treatment with the use of a synthetic adsorbent selected from among aromatic compound-based synthetic adsorbents and methacrylic compound-based synthetic adsorbents.

GALLOCATECHIN GALLATE-CONTAINING COMPOSITION

TECHNICAL FIELD

[0001] This invention relates to a composition comprising an agent having an antibacterial activity, such as (+)-epigallocatechin gallate (EGCG) mixed with its epimer gallicocatechin gallate (GCG), whereby the antibacterial activity of EGCG is enhanced, as well as foods and drinks containing the composition.

BACKGROUND ART

[0002] With the recent growing interest in health, attempts have been made to reduce the contents of salt and sugar in foods and drinks. As a result, a problem arises that humidity is elevated in foods, which facilitates the proliferation of microorganisms. It is reported that about 87% or more cases of food poisoning are caused by bacteria (Yoji Kato, Aug. 2001, *Gekkan Food Chemical*, published by Shokuhin Kagaku Shinbun-sha Inc.). Although refrigerated distribution systems have been developed in these days, it is still urgently required to ensure storage stability and safety of foods. For this purpose, it has been a common practice to use food additives, for example, preservatives such as sorbic acid (or potassium salt thereof), benzoic acid (or sodium salt thereof) and polylysine, and storage stability-improvers such as glycerine fatty acid esters, glycine and tea extract. Use of chemically synthesized preservatives, which are not always safe with regard to toxicity, skin irritation and allergy, is strictly regulated. Most of the existing storage stability-improvers comprise essential oil components as active ingredients, but these components can be used only in a limited scope or in a limited amount because of the distinctive, strong smell and low solubility in water. Further, tea extract has another problem that the bitterness and astringency of catechins contained therein become perceivable at a concentration where the tea extract can exhibit the antibacterial effect. Although there have been disclosed methods of using saccharides, for example, a method disclosed in JP-A-H8-298930 wherein dextran and an enzyme reaction are used, and a method disclosed in JP-A-H3-168046 wherein cyclodextrin is concomitantly used, and a method of using proteins (for example, a method disclosed in JP-A-H2-202900 wherein egg albumin, vegetable protein and so on are used, and a method disclosed in JP-A-2001-31669 wherein defatted egg yolk is concomitantly used), it is still required to develop a food additive capable of exerting an antibacterial activity at a lower concentration and being not restricted in terms of application scope or amount, thereby satisfying customers' demands for safety and reliability.

[0003] From the viewpoint of oral hygiene, on the other hand, oral bacteria cause serious problems of dental caries and periodontal disease. With regard to the pathogen of dental caries, it is recognized that dental caries falls within the category of bacterial infections based on the chemo-parasitic theory. According to this theory, the onset mechanism of dental caries is as follows. First, enzyme glucosyl transferase produced by oral streptococci, in particular, *Streptococcus mutans*, generates sticky, insoluble polysaccharides (glucans), utilizing sucrose in the mouth as the substrate. Due to the glucans thus formed, cells of the oral streptococci adhere to tooth surface to form massed bacte-

rias (dental plaque). In the dental plaque, various microorganisms live and proliferate and, as a result, produce organic acids as their metabolites. These organic acids lower the pH value on the tooth surface, and the enamel layer on the surface is decalcified. Dental caries thus occurs and proceeds. Further, it is reported that the plaque formation causes not only dental caries but also periodontal diseases and oral odor. Shigeaki Hamada, Feb. 1982, Iwanami Shinsho, *Mushiba no Dokushite Dekiruka*, published by Iwanami Shoten). A large number of attempts have been made to prevent dental caries and periodontal disease. That is, research and development has been carried out on antibacterial agents for inhibiting the proliferation of oral microorganisms, for example, green tea catechins; inhibitors for glucosyl transferase produced by oral microorganisms, for example, polyphenols from oolong tea; and noncarcinogenic sugars unusable as a substrate in plaque formation, for example, xylitol. In recent years, plant components, in particular, polyphenols, have attracted public attention as cariostatic agents. For example, leaves of tea plant (*Camellia sinensis*) contain polyphenols in an amount as much as 36% on a dry weight basis, and the major components of the polyphenols are called green tea catechins. Catechins include (+)-epicatechin (EC), (+)-epigallocatechin (EGC), (-)-epicatechin gallate (ECG) and (+)-epigallocatechin gallate (EGCG). Among all, it is known that EGCG exerts an antibacterial effect, an antimutagenic effect and a favorable effect on blood cholesterol level. JP-A-2001-97968 reports a method of producing EGCG. Further, (+)-catechin (C), EC, (+)-gallicocatechin (GC), EGC, ECG and EGCG are described as active ingredients of anti periodontal disease compositions in JP-A-H9-110687.

[0004] Alternatively, JP-A-H9-132532 describes a method of enhancing the antimicrobial activity of an antibiotic agent against methicillin-resistant *Staphylococcus aureus* (MRSA) by adding tea catechins and theaflavins. According to this report, EGCG and ECG can enhance the antibacterial activity of an antibiotic agent against MRSA.

[0005] To provide a highly safe and less expensive antibiotic agent originating in natural products, JP-A-H11-16418 discloses a method of producing a catechin-origin antimicrobial agent from green tea by the specified extraction conditions in terms of heating temperature, time and the like.

[0006] Furthermore, JP-A-2001-97968 as cited above discloses a method of purifying EGCG from a green tea extract, as well as an extract and a concentrate containing EGCG and GCG. However, an excellent anti *Streptococcus mutans* effect achieved by compounding EGCG and GCG is neither disclosed nor suggested in JP-A-2001-97968.

[0007] As discussed above, there has been found no antibacterial composition for preventing dental caries which is safe, inexpensive and satisfactory, and can be used without impairing the flavor of foods or drinks. =cl SUMMARY OF THE INVENTION

[0008] The present invention provides an antibacterial composition for safely and effectively reducing or preventing the onset of dental caries without impairing the flavor of foods or drinks, which composition is used in products such as foods and oral care goods which are mainly to be taken into human or animal bodies, or mainly to be used in the oral cavity.

DETAILED DESCRIPTION OF THE INVENTION

[0009] To search for a highly safe antibacterial agent with the use of the effect on *Streptococcus mutans* as an indication, the present inventors have conducted intensive studies and, as a result, surprisingly found that GCG (gallicocatechin gallate) has an activity of enhancing the antibacterial activity of green tea catechins such as EGCG, thereby completing the present invention.

[0010] Accordingly, the present invention relates to a composition comprising catechins mixed with an antibacterial effect enhancer gallicocatechin gallate.

[0011] The present invention also relates to an antibacterial composition against *Streptococcus mutans* and the like, containing an antibacterial-active fraction containing gallicocatechin gallate and green tea catechins obtained by extracting tea leaves with a solvent, adsorbing the solvent-extract from the tea leaves on synthetic adsorbent selected from among aromatic compound-based synthetic adsorbents and methacrylic compound-based synthetic adsorbents and then eluting the adsorbed components from the adsorbent, where the antibacterial activity of the green tea catechins is enhanced by the coexisting gallicocatechin gallate.

[0012] The term "green tea catechins" as used in the present invention means green tea polyphenol catechins known as a composition having very safe cariostatic and anti periodontal disease activity based on the antibacterial activity, and includes for example, C, EC, GC, EGC, ECG, EGCG, etc., or a mixture thereof. It is preferable that the green tea catechins contain at least EGCG.

[0013] The term "antibacterial catechins" as used in the present invention means catechins at least containing EGCG and having an antibacterial effect.

[0014] The composition according to the present invention is an antibacterial composition that is expected to be applicable in the fields of quasi drugs or foods, that exerts a highly safe, antibacterial, cariostatic, and anti periodontal disease effects, and that is aimed at improving the storage stability of drinks or processed foods.

[0015] Although the composition according to the present invention may be produced from any starting materials without restriction, preferably it derives from tea in view of stable supply. The "tea" as used herein includes, but is not limited to, unfermented tea products of green tea such as Sen-cha (Japanese green tea), Houji-cha (roasted green tea), gyokuro tea, Kabuse-cha (semi sun shaded tea), and Mushi-seicha (steamed tea); unfermented tea products of various Chinese type green tea (Kamairi-cha, pan fired tea), such as Ureshino-cha, Aoyagi-cha; semi-fermented tea products such as Hoshu-tea and oolong tea, fermented tea products such as black tea, Awa-bancha, Goishi-cha and Pu-er tea; Mate-tea and so on. Considering the presence of an epimer and the synergistic effect on catechins, oolong tea produced from *Camellia* leaves is preferably employed as a supply source.

[0016] The composition according to the present invention may be produced by mixing GCG with catechins having an antibacterial effect, such as EGCG. Alternatively, it can be obtained using any of the tea materials described above as a starting material, according to a conventional extraction

method. An extract from oolong tea using hot water or water-containing ethanol, etc., or an eluate which is obtained, as will be described in greater detail hereinafter, by dissolving or suspending said extract in water and then subjecting it to column chromatography using adsorptive resin such as DIAION HP-21 (manufactured by Mitsubishi Chemical Corporation, may be used.

[0017] The solvent used for extraction may be water alone, or an arbitrary mixture of water with one or more of polar solvents such as lower alcohols including methanol, ethanol, etc., and acetone. However, since the active ingredients according to the present invention cannot be efficiently extracted with a polar solvent alone, it is preferable to use a mixture of a polar solvent with water. Further, in such a solvent mixture, the content of the polar solvent is preferably not more than 90% by volume. Among these solvents, it is preferable to use water, ethanol or a mixture thereof from the viewpoint of safety, since the extract is to be finally formulated in oral care products or foods.

[0018] In the extraction step, the ratio of the tea leaves to the solvent is not particularly restricted. However, it is preferable to employ the solvent in an amount of 2 to 1,000 times by weight of the tea leaves, and in view of extraction procedure and efficiency, still preferably 5 to 100 times by weight of the tea leaves. It is convenient to carry out the extraction at a temperature of from room temperature to the boiling point of the solvent under atmospheric pressure. The extraction is preferably continued for a period of 10 minutes to 24 hours, though the extraction time varies depending on the extraction temperature.

[0019] To obtain an antibacterial fraction from the tea leaf extract thus obtained, the extract can be treated with a synthetic adsorbent. The synthetic adsorbent to be used in separating the tea leaf extract is, e.g., an aromatic compound-based synthetic adsorbent produced by polymerizing styrene and divinyl benzene or a methacrylic compound-based synthetic adsorbent produced by polymerizing methacrylic acid. Examples of commercially available aromatic compound-based synthetic adsorbents include DIAION HP20 and DIAION HP21 (manufactured by Mitsubishi Chemical Corporation), AMBERLITE XAD2 and AMBERLITE XAD 4 (manufactured by Rohm and Haas Company, USA) and so on, while examples of commercially available methacrylic compound-based synthetic adsorbents include DIAION HP1MG and DIAION HP2MG (manufactured by Mitsubishi Chemical Corporation), AMBERLITE XAD7 and AMBERLITE XAD 8 (manufactured by Rohm and Haas Company, USA) and so on.

[0020] It is preferable to carry out the synthetic adsorbent treatment by packing the synthetic adsorbent into a column, passing the tea leaf extract through the column and then washing the resin with water. When treating the tea leaf extract with the synthetic adsorbents, it is preferable to perform a pretreatment such as concentration under reduced pressure, to eliminate organic solvent from the extract, or sufficient dilution with water, to achieve complete fractionation of the extract. The gallicocatechin gallate can be eluted from the adsorbent with the use of, for example, a 30% aqueous methanol solution, though the invention is not restricted thereto.

[0021] It is still preferable to further purify the eluate using DIAION HP-21 (manufactured by Mitsubishi Chemi-

cal Corporation) having a smaller pore size as a column packing. In this way, high-molecular weight substances such as polyphenols having molecular weight of 2000 or more, which were adsorbed together with the antibacterial components on an adsorbent in the case of HP-20, are not adsorbed and pass as such, and therefore, catechins and their epimers with lower molecular weights can be selectively adsorbed and collected. If necessary, the eluate is further treated with DIAION HP-21 or SEPHADEX LH-20 (manufactured by Amersham-Pharmacia) and eluted with a water-containing alcohol, e.g., a 30% aqueous methanol solution or water-containing acetone, e.g., a 50% aqueous acetone solution. In this way, substances not contributing to the antibacterial activity, e.g., caffeine, can be removed, and the catechins, EGCG and its epimer gallicocatechin gallate, can be obtained at elevated concentration. The catechins, EGCG and its epimer gallicocatechin gallate according to the present invention, can be determined by the colorimetry using the phenol reagent (Folin-Ciocalteu reagent). However, it is advisable to use high-performance liquid chromatography (HPLC) to determine the composition in detail.

[0022] According to the above-described method, a composition is provided, wherein the antibacterial effect of EGCG is enhanced by GCG, and wherein the ratio EGCG:GCG ranges from 1.0:0.01 to 1.0:10.0, preferably from 1.0:0.05 to 1.0:2.0. From the fraction separated by the above-described method, a favorable GCG composition ratio can be determined using the antibacterial activity as an indication.

[0023] The tea leaf extract thus obtained may be used in any form, for example, a product as extracted or a product as eluted from the synthetic adsorbent, a concentrate thereof or a dried product obtained by removing solvents from the eluate. From the viewpoints of storage stability and safety for organic solvents, it is advisable to use the extract in the form of a dried product.

[0024] The composition according to the present invention may be used to reduce or prevent the onset of dental caries, by being added alone or together with various components already employed in the art, to drinks and foods of various purposes. To reduce or prevent the onset of dental caries means both to use the composition according to the present invention as oral care goods to suppress or prevent the onset of dental caries, and to regularly or intermittently take foods or drinks containing the composition according to the present invention over a certain period of time to reduce or prevent the onset of dental caries.

[0025] Preferred embodiments of the present invention include dental care goods such as toothpastes, mouth wash and troches, as well as additives to foods such as sweeteners such as sucrose, sweetened bean pastes, Castella cakes, mizu-yokan (soft adzuki-bean jelly), derayaki (bean-jelly pancake) coating, sponge cakes, butter cakes, bavaiois, custard cream, butter cream, custard pudding, cookies, sweet buns, steamed buns, jams, lactic acid bacteria drinks, carbonated drinks, coffee drinks, coffee jelly, caramel candies, ice creams, chewing gums, juice, candies and chocolates.

[0026] To produce these oral care goods or foods containing the cariostatic agents, components commonly employed in the art can be selected and used appropriately depending on the product types. For example, oral care goods may optionally contain calcium carbonate, dibasic calcium phos-

phate, silicic anhydride, magnesium carbonate, glycerine, sorbitol, propylene glycol, polyethylene glycol, carboxymethylcellulose, methyl cellulose, sodium alginate, carrageenan, carboxyvinyl polymer, sodium dioctylsulfosuccinate, sodium lauryl sulfate, sodium dodecylbenzenesulfonate, butyl parahydroxybenzoate, hinokitiol, allantoin, glycyrrhizin, alcohols, gum arabic, starch, corn starch, saccharin sodium, stevioside, glucose, lactose, magnesium stearate, monopotassium phosphate, dipotassium phosphate, menthol, eucalyptus oil, peppermint, spearmint, colorants, as well as fluorides such as sodium fluoride and sodium monofluorophosphate, anti-inflammatory agents such as lysozyme chloride and azulene, sodium chloride and so on.

[0027] On the other hand, foods may be produced by optionally blending commonly employed food materials such as glucose, fructose, sucrose, maltose, sorbitol, stevioside, corn syrup, lactose, citric acid, tartaric acid, malic acid, succinic acid, lactic acid, L-ascorbic acid, dl- α -tocopherol, sodium erythorbate, glycerine, propylene glycol, glycerine fatty acid esters, polyglycerine fatty acid esters, sucrose fatty acid esters, sorbitan fatty acid esters, propylene glycol fatty acid esters, gum arabic, carrageenan, casein, gelatin, pectin, agar, vitamin B family, nicotinic acid amide, calcium pantothenate, amino acids, calcium salts, colorants, flavoring agents and preservatives.

[0028] In the case of adding sugar together with a cariostatic agent to give such a cariostatic food, as will be shown in EXAMPLES by adding the composition according to the present invention to a food, a cariostatic sugar can be used as a substitute, as will be shown in EXAMPLES 6 to 8.

[0029] Since tea has been widely consumed all over the world from ancient times, there is no trouble with the fraction obtained from tea leaf extract in terms of safety. However, considering the flavor, smell, color tone, etc. of the product, it is preferred to add the composition according to the present invention (including the cariostatic composition) to the food and drink of the present invention at a concentration of 0.0001 to 0.5%, still preferably 0.01 to 0.2%, on a dry weight basis. It is also preferable to control the concentration in a food within the range as specified above, in use. Further, according to the present invention, it is also possible to reduce an amount of antibacterial catechins owing to the effect of gallicocatechin gallate.

ADVANTAGES OF THE INVENTION

[0030] The composition according to the present invention shows a strong antibacterial activity against *Streptococcus mutans* which is the major causative bacterium of dental plaque formation inducing dental caries and periodontal diseases. The component employed in the present invention is extremely safe and the composition can be supplied in a large amount as cariostatic and anti periodontal disease composition, because the ingredients of the composition originate in tea, which has been widely consumed from ancient times. Accordingly, the present invention appears to contribute to improvement in oral hygiene and, furthermore, is expected to be applicable to the field of general foods, and therefore, industrially very useful.

[0031] Next, the present invention will be illustrated in greater detail by reference to the following EXAMPLES. However, it is needless to say that the present invention is not restricted to these EXAMPLES.

EXAMPLE 1

Enhancement of Antibacterial Effect by Mixing
EGCG and GCG

[0032] *Streptococcus mutans* (MT8148R) was cultured in a brain heart infusion medium (BHI, manufactured by Difco) at 37° C. for 18 hours. After collection of the cells by centrifugation, the precipitate was washed three times with a phosphate buffer solution (PBS, pH 6.8). Then the cells were suspended to give an absorbance of 0.5 at 550 nm. Thus, about 2×10^7 colonies per mL (expressed in colony forming unit: CFU) were formed. Next, an equal amount of a previously prepared sample solution was added to the suspension and the resultant mixture was allowed to stand at 37° C. for 1 hour. 0.1 mL of this liquid mixture or the same mixture seriously 10-fold diluted was sowed on a Mitis salivarius agar medium (MS agar medium, manufactured by Difco). After culturing at 37° C. for 2 days, the colonies thus formed were counted. The antibacterial activity was indicated in the logarithm of CFU of test group/CFU of control lot (i.e., the reducing ratio).

[0033] The mixing ratio of EGCG to GCG (manufactured by Sigma) was varied so as to adjust the final concentration of the sample to 1 mg/mL and thus the antibacterial activity was examined. Compared with the samples containing EGCG or GCG alone, the mixtures of them showed enhanced antibacterial activities. In particular, the sample having an EGCG:GCG ratio of 1.00:0.45 showed an activity $10^{1.25}$ times higher (about 15-fold) than that of the sample containing EGCG alone. Table 1 summarizes the results.

TABLE 1

Ratio		Antibacterial
EGCG	GCG	activity
1.00	0.00	-3.17
1.00	0.05	3.4
1.00	0.10	-4.47
1.00	0.15	-4.4
1.00	0.20	-4.44
1.00	0.25	-4.75
1.00	0.30	-4.16
1.00	0.35	-4.22

EXAMPLE 2

Fractionation of Oolong Tea Extract

[0034] To oolong tea leaves was added 10 volumes of a 45% (w/w) aqueous ethanol solution. After immersion of the tea leaves at room temperature for 1 day, the mixture was filtered and the extract thus obtained was powdered by concentration under reduced pressure and freeze-drying. To the powder thus obtained, 100 volumes of deionized water were added and the resultant suspension was passed through a DIAION HP-21 column (manufactured by Mitsubishi Chemical Corporation). After washing with deionized water, elution was carried out with the use of a 30% aqueous methanol solution (passing speed: SV=3, passing volume: 5-bed volumes each time). The eluate obtained using the 30% aqueous methanol solution was concentrated under reduced pressure and freeze-dried to give a powder.

[0035] Using the obtained powder, a 50% DMSO solution was prepared and analyzed by high-performance liquid

chromatography (analyzer: Alliance Photodiode Array System, manufactured by Waters; column: Develosil C30-UG-5, 4.6×150 mm, manufactured by Nomura Kagaku Co., Ltd.; mobile phase and elution conditions: linear gradient from Solution A (0.05% trifluoroacetic acid) to Solution B (50% acetonitrile-0.05% trifluoroacetic acid) within 20 minutes; flow rate: 1 mL/min; column temperature: 40° C.). C, CG, EC, GC, EGC, EGCG, GCG and ECG (manufactured by Sigma) were used as standards and the weights of the catechins contained were determined from the respective calibration curves. The composition ratio is shown in Table 2, with the major component EGCG being taken as 1.00.

TABLE 2

Composition ratio of catechins Composition ratio of catechins by weight							
EGCG	EGC	GCG	ECG	C	EC	GC	CG
1.00	0.34	0.10	0.10	0.07	0.1	0.1	0.1

In this Table, "0" means a trace amount which is too small to indicate numerically.

EXAMPLE 3

[0036] Toothpaste:

(component)	(parts by weight)
Dibasic Calcium phosphate	42.0
Glycerine	18.0
Carbamide	0.9
Sodium lauryl sulfate	1.2
Saccharin Sodium	0.9
Butylenediol	0.05
Tea leaf extract*	0.2
Flavoring agent	0.1
Water	the balance
Total	1

*The oolong tea leaf extract powder obtained in EXAMPLE 2 (the same will be applied hereinafter).

EXAMPLE 4

[0037] Mouth wash:

(component)	(parts by weight)
Sodium lauryl sulfate	1
Glycerine	1
Sorbitol	2
Butylenediol	0.05
Tea leaf extract	0.2
Flavoring agent	0.05
Saccharin sodium	0.04
Water	the balance
Total	100.0

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCION DE NUEVAS CREACIONES**

2020
Bogotá, D.C.,

Abogado: **JUAN PABLO CADENA SARMIENTO**

ASUNTO: Radicación No. 07-63487
Trámite 002
Evento 378
Actuación 519
Oficio **0 0 4 0 1**
Folios 018

Patente de Invención ☐
Vía Nacional ☐
Vía PCT (fase nacional) ☐

Cap. I ☒

Cap. II ☐

No. Solicitud Internacional: PCT/US2005/046242
Fecha de Presentación Internacional: 2005-12-21

Como resultado del Examen de Fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se comunica:

1. Documentos estudiados:

Descripción: Folios 25 a 34 como se radicó inicialmente.
Reivindicaciones: Folios 35 a 37 como se radicó inicialmente.
Prioridad: US2004 60639079 (2004-12-23)
US2004 60639080 (2004-12-23)
US2005 11256860 (2005-10-24)

2. Objeto de la Invención

Titulo de la invención Composición de cuidado bucal que contiene extracto de camellia no oxidado

Problema Técnico Planteado Necesidad de composiciones de cuidado oral con propiedades antiinflamatorias, antibacteriales y antioxidantes.

Solución Composición de cuidado bucal que contiene extracto de camellia, triclosan y vitamina E

IPC: A61K8/97; A61Q11/00

3. Excepciones a la Patentabilidad (Art 20 D 486 literal (d))

Las reivindicaciones 18 a 23 y 25 a 29 reclaman un método para tratar e inhibir una condición inflamatoria bucal y proporcionar una acción antioxidante; lo anterior corresponde a un método de tratamiento por tal razón **no es patentable**.

4. Análisis de la Solicitud de Patente

4.1. Reivindicaciones (Art 30 D 486, Art 22 PCT)

Las Reivindicaciones 1, 2, 4 a 6 y 9 a 13 no son claras porque:

El término: “aproximadamente” es impreciso por lo cual no permite distinguir la invención del estado de la técnica. Se sugiere sustituirlo por un término preciso o un rango concreto.

Reclama una composición la cual está caracterizada por extracto de camelia en una “cantidad mínima que exhibe una actividad antiinflamatoria”. Esto no define claramente la invención y hace que esta sea ambigua, pues una cantidad mínima es una expresión indeterminada. Se sugiere sustituir esta expresión por términos precisos o rangos concretos de valores.

La Reivindicación 9 no es concisa porque:

Hace referencia a una composición que contiene un extracto de camellia en una proporción del 0.001% al 20%. Dicha proporción no limita el objeto de la invención. Se sugiere limitar a una generalización razonable de la proporción de dicho extracto de camellia de acuerdo a lo expuesto en la memoria descriptiva.

5. Determinación del Estado de la Técnica

El Estado de la Técnica se determinó con base en la fecha de la solicitud prioritaria (2004-12-23) y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

Item	Documento	Título	Fecha de Publicación
D1	WO0117494	Oral compositions comprising tea polyphenol	2001-03-15
D2	JP61197510	Composition for oral purposes	1986-09-01
D3	WO03094878	Gallatochatequin gallate containing composition	2003-11-20

D1: Una composición de cuidado oral que contiene extracto de te, un agente antibacterial como lo es el triclosan para la prevención de caries, inflamación bucal y con efecto antibacterial.
D2: Composición de cuidado oral que contiene un derivado de nitroimidazol como agente antibacterial y y el extracto de hojas de camellia sinensis.
D3: : Composición de cuidado oral antibacterial que contiene un polifenoles de camellia sinensis dentro de los que se encuentran epicatequina, epigalocatequina, galato de epicatequina y galato de epigalocatequina.

6. Análisis de Patentabilidad (Art 14 D486)

6.1. Novedad (Art18 D486)

Respecto a la solicitud en estudio:
La **reivindicación 1** dice: “Una composición oral para el tratamiento, la inhibición o la reducción de una condición inflamatoria bucal que comprende:

- un **extracto de Camellia** que incluye al menos aproximadamente un 30 % de "galato de epigalocatequina", al menos aproximadamente un 50 % de total de catequinas, y al menos aproximadamente un 60 % de total de polifenoles; y
- un **agente anti bacterial no catiónico** substancialmente insoluble en agua.

Comparación de las características técnicas **esenciales**, con las del Estado de la Técnica:

Características esenciales	D1	D2	D3
Composicion oral	✓	✓	✓
Extracto de camelia			
- galato de epigalocatequina	✓	✓	✓
- catequinas			
- polifenoles			
Agente antibacterial no cationico	✓	✓	✓

Respecto al estado de la Técnica, las características **esenciales** de la composición de la reivindicación 1 habían sido divulgadas previamente en **D1**, es decir: una composición de cuidado oral que contiene:

- **extracto de te** proveniente de hojas de **camellia sinensis** (ejemplo 1; pagina 4, línea 23 a 30) las cuales contienen diferentes tipos de **polifenoles**, dichos polifenoles se caracterizan por ser **catequinas** (Ejemplo 1; pagina 4, línea 23 a 30) , las cuales a su vez incluyen epicatequina, epigalocatequina, galato de epicatequina y **galato de epigalocatequina** (pagina 5, línea 3 a 5) **en proporciones entre el 20 y el 40%** (pagina 4, línea 23 a 30).
- Un **agente antibacterial** (Ejemplo 1; reivindicación 6) de tipo no catiónico como lo es el **triclosan**

Debido a lo anterior reivindicación **no es nueva**.

Respecto a la solicitud en estudio:

La **reivindicación 5** dice: La composición oral de acuerdo con la reivindicación 1, en donde la Vitamina E se encuentra presente en la composición en una cantidad de aproximadamente un 0,1 % a aproximadamente un 4 % en peso.

Respecto al estado de la Técnica, las características **esenciales** de la composición de la reivindicación 2 habían sido divulgadas previamente en **D1**, es decir: una composición de cuidado oral que contiene:

- **extracto de te** proveniente de hojas de **camellia sinensis** (ejemplo 1; pagina 4, línea 23 a 30)
- Un **agente antibacterial** (Ejemplo 1; reivindicación 6) de tipo no catiónico como lo es el **triclosan**
- Y adicionalmente 0.01% a 0.10% de **vitamina E** (Ejemplo 1; pagina 4, línea 23 a 30)

Las reivindicaciones dependientes 2 – 15 no mencionan alguna característica que haga nueva a la composición de la reivindicación 1, por lo cual se considera que no son nuevas.

7. Conclusión

Los requisitos de Patentabilidad de la presente Solicitud se encuentran afectados así:

Nº	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	WO0117494	1-15	Novedad

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 60 días contados a partir de la fecha de 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 Única N° 10 de 2001.



JOSÉ LUIS SALAZAR LÓPEZ
Director de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha _____

CONCEPTO TECNICO NUMERO:0035	EXAMINADOR TÉCNICO Código:202093
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