

2185399

STABILIZED DENTAL CREAM

The present invention relates to dental cream packaged in plastic laminate tube, mechanical
5 dispenser, flexible sachet or the like. In particular it relates to dental cream in compatible contact with polyolefin surface of a package such as a plastic laminate dental cream tube, mechanical dispenser or flexible sachet.

10 Dental creams have been packaged for many years in flexible metal tubes such as wax lined lead tubes, unlined aluminium tubes or aluminium tubes having an epoxy resin lacquer coating thereon. In recent years flexible form-retaining laminated plastic tubes have
15 been increasingly used.

Plastic laminated dental cream tubes typically comprise an inner polyolefin resin layer which is in direct contact with the dental cream and at least one intermediate layer, including an aluminium foil layer
20 which inhibits loss of flavour from the dental cream. Desirably, an intermediate paper layer which provides stiffness to the tube is also present. The outer layers are typically of polyolefin resins, one of which may be coloured white and bears printed indicia with a
25 clear polyolefin laminate overlay to protect the indicia. Additional intermediate laminate layers of flexible plastic may also be present.

Mechanical dental cream dispensers may also have a polyolefin surface in contact with dental cream
30 contained therein. In fact, the polyolefin itself may be the housing of the dispenser. Flexible sachet packets may also have a polyolefin surface in contact with dental cream.

Dental creams typically contain a liquid vehicle of water and humectant, a gelling agent solid vehicle

and a water-soluble dental polishing agent. Dental creams composed of such materials wherein the humectant comprises glycerine and sorbitol and the polishing material is at least in major part a water-insoluble alkaline earth metal salt or an alpha alumina trihydrate have been successfully packaged in flexible metal toothpaste containers including aluminium tubes having an internal coating of an epoxy resin lacquer layer. However, it is observed that when such dental creams are packaged in containers having an interior polyolefin surface such as plastic laminated dental tubes, mechanically operated dental cream dispensers or flexible sachets, that syneresis occurs and liquids separate from solids, rendering the dental cream undesirable, when the polishing material is an alkaline earth metal salt or an alpha-alumina trihydrate with the pH of the dental cream reduced with a water-soluble material which provides phosphate ion.

The present invention substantially reduces or prevents phase separation of a dental cream packaged in contact with a polyolefin material.

In prior developments of dentifrices vegetable oils have occasionally been used for various purposes. For instance, US Patent 1,551,638 to Brady describes a toothpaste containing glycerine, gum tragacanth, calcium carbonate, essential oils (clove and cinnamon) and Soap Lake salts from Soap Lake in Grant County, Washington State, USA, which contain large amounts of sodium carbonate, sodium chloride and sodium sulphate, wherein the Soap Lake salts are saponified with oils such as coconut oil and peach kernel oil, which are vegetable oils.

Further in US Patent 2,090,437 to Woldman, highly

5 purified neutral oils of the glycerid type are described as being oily preserving liquids which do not leave the teeth and gums greasy. Salad oils are stated to have this property. In addition these oils are described as being compatible with sodium perborate. Olive oil, peanut oil and especially cottonseed oil are indicated to be desirable.

10 In US Patent 1,488,097 to Creger, the vegetable oil, oil of aniseed, is set forth as an ingredient in an anti-pyorrhea toothpaste which also contains gum tragacanth, glycerine and calcium carbonate as well as oil of eucalyptus as a gummy exudation of fluid
15 extracts from the bark of the Eucalyptus rostrata, commonly known as red gum, and redistilled oil of peppermint, an essential oil.

In US Patent 1,943,467 to Bley antiseptic
20 dentrifrises are described which may include a variety of oils as modifying and flavouring compounds. Disclosed oils include peppermint oil, peppermint oil substitutes, clove oil, cassia oil, cinnamon oil, thyme oil, nutmeg oil, caraway oil, bergamot oil, rose-geranium oil, neroli oil, lavender oil and lemon oil.

25 In US Patent 2,089,529 to Behr, oils including vegetable oils are described as imparting desired consistency to toothpaste. Olive oil is particularly indicated as a toothpaste containing gum tragacanth and calcium carbonate.

30 In US Patent 2,216,485 to Brandt, sulphonated petroleum extracts are stated to be used in manufacturing and stabilizing aqueous dispersions of water insoluble or nearly water insoluble substances such as mineral oils, vegetable oils etc. In illustrative examples coconut oil fatty acid is

included in a lather shaving cream while a milk of magnesia dental cream contains sulphonated mineral oil extract.

US Patent 4,523,342 to Weiss et al describes compositions including toothpastes containing vegetable oils to reduce halitosis. Humectant materials are not disclosed.

In accordance with certain of its aspects, the present invention relates to a packaged stabilized dental cream packaged in a container, the inner resin surface of which is polyolefin, the said stabilized dental cream comprising at least about 20% by weight of a liquid vegetable oil, the weight ratio of glycerine to sorbitol being from 0.25:1 to about 3:1 and the amount of said vegetable oil being about 0.1-5%, by weight of gelling agent, about 20-75% by weight of a dentally acceptable water-insoluble polishing material, at least a major portion of which is a water-insoluble alkaline earth metal salt or is alpha-alumina trihydrate and when alpha-alumina trihydrate is present as the major portion of the polishing material, there is present a water-soluble material to reduce the pH of the dental cream to about 6-8 which provides phosphate ion.

In dental cream formulations, the liquids and solids are necessarily proportioned to form a creamy mass of desired consistency which is extrudible from its package. The liquids in the present dental cream comprise chiefly water, glycerine and sorbitol.

The total liquid vehicle comprises at least about 20% by weight of the formulation. It is preferred to use also a gelling agent in dental creams such as the natural and synthetic gums and gumlike materials, e.g. carrageenans such as Irish moss, iota-carrageenans, gum tragacanth, sodium carboxymethyl cellulose,

hydroxyethyl cellulose, polyvinyl pyrrolidone, sodium alginate, guar gum, starch, xanthan and the like, including mixtures thereof. Irish Moss, sodium carboxymethyl cellulose and hydroxyethyl cellulose including mixtures thereof are compatible particularly and are preferred gelling agents when the major polishing agent is water-insoluble alkaline earth metal salt, iota-carrageenan is also a preferred gelling agent. The gum content is usually in an amount of about 0.05-10% and preferably about 0.5-5% by weight of the formulation.

Water is generally incorporated into the dental cream in an amount of about 10-50% by weight, preferably about 15-35%. Glycerine and sorbitol together generally comprise about 15-50% by weight, preferably about 20-35% of the dental cream, with the weight ratio of glycerine to sorbitol being from about 0.25:1 to about 3:1, typically from about 0.25:1 to about 0.8:1 and preferably from about 0.6:1 to about 0.8:1. Amounts of sorbitol as used herein are of sorbitol syrup, as commercially available, that is 70% by weight sorbitol in 30% by weight of water.

Vegetable oils disperse readily in the liquid vehicle and while providing desirable sensory effects are also effective to prevent the dental cream from undergoing syneresis when in direct contact with a polyolefin resin surface of a dental cream package. Vegetable oils are obtained by extraction of oil from seeds of plants, particularly vegetable or fruit plants. They are well described in Vegetable Fats and Oils, Jamieson, Chemical Catalog Co., Inc. New York, New York, 1970. Many particular vegetable oils are listed in appendix Tables 12, 16, 17 and 18 of

Vegetable Fats and Oils (pages 414-423) and in Table 6.1 of Food Industries Manual, 20th edition (pages 200-201). Of the vegetable oils, coconut oil, palm oil, peanut oil and safflower oil are observed as particularly effective in reducing syneresis with coconut oil being preferred, based upon overall performance. Vegetable oil is employed in the dental cream in an amount of about 0.1-5% by weight, preferably about 0.5-2%.

Dentally acceptable water-insoluble polishing agent is present in the dental cream in an amount of 20-75% by weight, preferably about 35-70%. At least the major portion, that is, about 50-100% of the polishing material is water-insoluble alkaline earth metal salt or alpha-alumina trihydrate.

Typical water-insoluble alkaline earth metal salts include dicalcium phosphate dihydrate, anhydrous dicalcium phosphate, calcium carbonate, tricalcium phosphate, calcium pyrophosphate, dimagnesium phosphate trihydrate and magnesium carbonate including mixtures thereof. Most preferably, calcium salt, particularly dicalcium phosphate dihydrate or a mixture of dicalcium phosphate dihydrate and anhydrous dicalcium phosphate, is present.

Dentally acceptable water-insoluble alpha-alumina used in toothpaste is typically employed in small particle size, e.g. wherein at least about 85% of the particles are smaller than 20 microns and is preferably hydrated, such as that classified as gibbsite (alpha alumina trihydrate) and normally represented chemically as $\text{Al}_2\text{O}_3 \cdot 3\text{H}_2\text{O}$ or $\text{Al}(\text{OH})_3$. The average particle size of gibbsite is generally about 6 to 9 microns. However, larger particle size alpha-alumina trihydrate, e.g.

wherein 20-50% of the particles exceed 20 microns in size, may also be used. A particularly desirable grade of alpha-alumina trihydrate, available from Alcoa as C-333 is a fine grade of gibbsite having the following size distributions:

	<u>Microns</u>	<u>Percent</u>
10	less than 30	94-99
	less than 20	85-93
	less than 10	56-67
	less than 5	28-40

Unless the pH of the dental cream is adjusted, dental cream containing a substantial amount of alpha-alumina trihydrate is generally highly alkaline, e.g. about pH 9-10.5. Accordingly acidic materials are often added to such dental creams in order to reduce the pH, typically to about 6 to 8. Water-soluble phosphate materials, particularly inorganic phosphate materials are effective to produce such reduction in alkalinity. Such materials include orthophosphates particularly orthophosphoric acid and alkali metal or ammonium monoacid orthophosphates or diacid orthophosphates. Sodium diacid orthophosphate and hydrates thereof are preferred. The amount of these materials is that sufficient to adjust the pH to about 6-8: e.g. sodium diacid orthophosphate (monohydrate or anhydrous) is typically present in an amount of about 0.15-0.50% by weight. Such phosphate pH adjusting materials render the dental creams subject to syneresis when in contact with a polyolefin resin surface unless additive is present to prevent syneresis.

When water-insoluble alkaline earth metal salt is

the major component of the polishing material, alpha-alumina trihydrate, calcined alumina or other additional polishing agent may optionally be present in a minor amount, for instance in a weight ratio of alkaline earth metal salt to alumina material of about 2.5:1 to about 4:1, the total amount of polishing material in the dental cream being about 25-75% by weight.

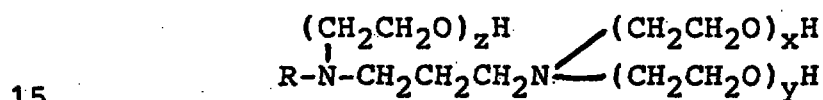
When alpha-alumina trihydrate is the major component of the polishing material, the minor portion of the polishing material, if present, typically comprises about 5-20% by weight of the polishing material, and may be polishing agent such as dicalcium phosphate dihydrate, anhydrous dicalcium phosphate, calcium carbonate, tricalcium phosphate, calcium pyrophosphate, dimagnesium phosphate trihydrate, magnesium carbonate, calcined alumina, zirconium silicate or insoluble sodium metaphosphate.

Organic surface-active agents may be used in the dental cream of the present invention to achieve increased prophylactic action, assist in achieving thorough and complete dispersion of the compositions of the present invention throughout the oral cavity, and render the dental creams more cosmetically acceptable. The organic surface-active material may be anionic, nonionic, ampholytic or cationic in nature, but it is preferred to employ as the surface-active agent a deterative material which imparts to the composition deterative and foaming properties. Suitable types of such detergents are water-soluble salts of higher fatty acid monoglyceride monosulphates, such as the sodium salt of the monosulphated monoglyceride of hydrogenated coconut oil fatty acids, higher alkyl sulphates, such

as sodium lauryl sulphate, alkylaryl sulphonates, such as sodium dodecyl benzene sulphonate, olefinsulphonates, such as sodium olefin sulphonate in which the olefin group contains 12-22 carbon atoms, higher alkyl sulphoacetates, higher fatty acid esters of 1,2-dihydroxy propane sulphonates, and the substantially saturated higher aliphatic acyl amides of lower aliphatic amino carboxylic acid compounds such as those having 12-16 carbon atoms in the fatty acid, alkyl or acyl radicals and the like. Examples of the last mentioned amides are N-lauroyl sarcosine, and the sodium, potassium, and ethanolamine salts of N-lauroyl, N-myristoyl or N-palmitoyl sarcosine, which should be substantially free from soap or similar higher fatty acid material which tends to substantially reduce the effect of these compounds in compositions of the present invention. The amides are particularly advantageous since they exhibit a prolonged and marked effect in the inhibition of acid formation in the oral cavity due to carbohydrates breakdown in addition to exerting some reduction in the solubility of tooth enamel in acid solutions. Another desirable material is a long chain fatty acid sodium monoglyceride sulphonate used alone or in combination with sodium lauryl sulphate.

Other particularly suitable surface-active materials include nonionic agents such as condensates of sorbitan monostearate with approximately 20 moles of ethylene oxide, condensates of ethylene oxide with propylene glycol ("Pluronic" (Registered Trade Mark) materials) and amphoteric agents such as long chain (alkyl) amino-alkylene alkylated amine derivatives, which are available under the trade mark "Miranol" (Registered Trade Mark) such as Miranol C₂M. Cationic

5 surface-active germicides and antibacterial compounds
 such as di-isobutyl phenoxy ethoxy ethyl dimethyl
 benzyl ammonium chloride, benzyl dimethyl stearyl
 ammonium chloride, benzyl diethyl stearyl ammonium
 10 chloride, tertiary amines having one fatty alkyl group
 (of from 12-18 carbon atoms) and two (poly) oxyethylene
 groups attached to the nitrogen (typically containing a
 total of from about 2 to 50 ethanoxy groups per
 molecule) and salts thereof with acids, and compounds
 of the structure



where R represents a fatty alkyl group containing from
 about 12 to 18 carbon atoms, and x, y and z total 3 or
 higher, as well as salts thereof with mineral or
 20 organic acids, may also be used. It is preferred to
 use from about 0.05 to 5% by weight of the foregoing
 surface-active materials in the dental cream. It is
 most preferred that the surface-active agent be an
 anionic material, particularly sodium lauryl sulphate.

25 The dental cream suitably may also contain a
 fluorine-containing compound having a beneficial effect
 on the care and hygiene of the oral cavity, e.g.,
 diminution of enamel solubility in acid and protection
 of the teeth against decay. Examples thereof include
 30 sodium fluoride, stannous fluoride, potassium fluoride,
 potassium stannous fluoride ($\text{SnF}_2 \cdot \text{KF}$), sodium
 hexafluorostannate, stannous chlorofluoride, sodium
 fluorozirconate, and sodium monofluorophosphate. These
 materials which disassociate or release fluorine-
 containing ions in water, suitably may be present in an

effective but non-toxic amount, usually within the range of about 0.01 to 1% by weight of the water soluble fluorine content thereof.

5 The preferred fluorine-containing compound is sodium monofluorophosphate typically present in an amount of about 0.076 to 7.6% by weight, preferably 0.76%. A mixture of sodium monofluorophosphate and sodium fluoride is also desirable, for instance in a
10 weight ratio of about 2:1 based on fluoride.

Any suitable flavouring or sweetening materials may be employed in formulating a flavour for the compositions of the present invention. Examples of
15 suitable flavouring constituents include the flavouring oils e.g. oils of spearmint, peppermint, wintergreen, sassafras, clove, sage, eucalyptus, marjoram, cinnamon, lemon and orange, as well as methyl salicylate. Suitable sweetening agents include sucrose, lactose,
20 maltose, xylitol, sodium 6-methyl-3,4-dihydro-1,2,3-oxathiazine-4-one, sodium cyclamate, perillartine and sodium saccharin. Suitably, flavour and sweetening agents may together comprise from about 0.01 to 5% or more of the compositions of the present invention.

25 Various other materials may be incorporated in the dental cream. Examples thereof are colouring or whitening agents or dyestuffs, anti-corrosive agents, silicones, chlorophyll compounds, ammoniated materials such as urea, diammonium phosphate and mixtures thereof and other constituents. Whitening agents, such as
30 titanium dioxide, typically in amounts of about 0.5-2%, may be beneficial to the appearance of the dental composition, since upon aging, some discolouration may occur.

The adjuvants are incorporated in the compositions

of the present invention in amounts which do not substantially adversely affect the properties and characteristics desired and are selected and used in proper amounts depending upon the particular type of composition involved.

Antibacterial agents may also be employed in the oral compositions of the present invention in an amount of about 0.01-5% by weight. Typical antibacterial agents include:

N^1 -(4-chlorobenzyl)- N^5 -(2,4-dichlorobenzyl) biguanide;
p-chlorophenyl biguanide;
4-chlorobenzhydrylguanylurea;
 N -3-lauroxypropyl- N^5 -chlorobenzylbiguanide;
1,6-di-chlorophenylbiguanidohexane;
1,6-bis-(2-ethylhexylbiguanide) hexane;
1-(lauryldimethylammonium)-8-(p-chlorobenzyl dimethylammonium) octane dichloride;
5,6-dichloro-2-guanidinobenzimidazole;
 N^1 -p-chlorophenyl- N^5 -laurylbiguanide;
5-amino-1,3-bis(2-ethylhexyl)-5-methylhexahydro-pyrimidine and their non-toxic acid addition salts.

In dental creams containing an alkaline earth metal salt polishing agent there may be employed also various calcium and magnesium ion suppression agents for adjustment of physical properties of the compositions. Suitable agents are the water-soluble inorganic polyphosphate salts, such as tetrasodium pyrophosphate or disodium diacid pyrophosphate, with the partially neutralized or acid polyphosphate preferred. Other suitable agents are the alkali metal, preferably sodium, salts of citric acid. In general, such compounds will be a minor amount or proportion of

the formulation. The precise amount will vary depending upon the specific formulation, such as the physical characteristics of the dental cream, but will usually be from about 0.1% to about 3% by weight.

The dental creams should have a pH practicable for use. A pH range of 5 to 10 is particularly desirable for water-insoluble alkaline earth metal dental cream. The reference to pH is meant to be the pH determination directly on the dental cream. If desired, materials such as citric acid may be added to adjust the pH to say 6 to 7. For alpha-alumina trihydrate dental cream there is present a water-soluble material to reduce the pH of the dental cream to about 6-8, which provides phosphate ion.

The package into which the dental cream is incorporated may be any polyolefin laminate dental cream tube. For instance, the tube may be as elementary as is described in US Patent 3,260,410 to Brandt et al. As described in the example thereof, an aluminium foil base having a thickness of about 0.0013cm was heated to a temperature of approximately 177°C, and one face of the heated foil was contacted by an extrudable film of a random copolymer of ethylene and acrylic acid (acid content 3±0.5% and melt index 8±1), while the opposite surface thereof had placed thereagainst a film of low density polyethylene.

Using driven rolls a laminated base was obtained in which the copolymer layer was about 6 mils and the polyethylene layer was approximately 5 mils in thickness. The base was then shaped into tubular form and sealed.

After severing the tubular form into tube bodies, the tubes can be packed with the dental cream of the

present invention.

5 Polyolefin laminate dentifrice tubes containing more intermediate layers may also be successfully used with the dental cream of the present invention without undergoing syneresis. For instance, the multiple layer flexible sheet structure for dental cream tubes described as "Prior Art" in US Patent 4,418,841 to Eckstein may be employed as well as the more crack resistant structures described therein. In fact, dental creams of the present invention packed in tubes of sheet material identified as Prior Art A and A-1 in 10 US Patent 4,418,841 are very satisfactory and undergo substantially no syneresis. Such tubes A and A-1 are comprises of layers as set forth below, in the order of the outermost layer to innermost layer.

	<u>A</u>	<u>A-1</u>
20	1.5 mil LDPE	1.5 mil LDPE
	2.0 mil Pigmented LDPE	2.0 mil Pigmented LDPE
	1.6 mil Paper	1.6 mil Paper
	0.7 mil LDPE	2.0 mil LDPE
	3.3 mil EAA	1.0 mil OPP
25	0.7 mil Foil	1.0 mil EAA
	2.0 mil EAA	0.7 mil Foil
	<u>1.2 mil LDPE</u>	2.0 mil EAA
	13.0 mil Total	<u>1.2 mil LDPE</u>
		13.0 mil Total

30 In A and A-1 the abbreviations have the following meanings:

LDPE low density polyethylene
 EAA ethylene acrylic acid
 OPP oriented polypropylene

5 Mechanically operated dispensers, such as the
dispenser for, in particular, pasty substances,
described in US Patent 4,437,591 to von Schuckmann, the
disclosure of which is incorporated herein by
reference, may also be used with the practice of the
present invention. The housing of such dispensers is
10 commonly composed of a polyolefin resin such as
polypropylene. Thus the housing resin is in essence a
layer, the inner surface of which is in contact with
dental cream. When the dental cream of the present
invention is packaged in such a polypropylene
15 mechanical dispenser, it undergoes substantially no
syneresis.

The advantages of the invention are also present
when the dental cream is packed in a flexible sachet
having a polyolefin surface, typically of low density
or medium density polyethylene.
20

The invention may be put into practice in various
ways and a number of specific embodiments will be
described to illustrate the invention with reference to
the accompanying examples.

25

EXAMPLES 1A TO 1D

The following dental creams having the
compositions set out in Table 1 below are prepared to
30 creamy consistencies and packed into tubes each of
laminated structures A and A-1 set forth above:

Table 1

		<u>Parts</u>	
5	<u>Example</u>	<u>1A</u>	<u>1B</u>
	<u>Ingredient</u>		
	Glycerine	8.000	8.000
	Sorbitol (70%)	15.800	15.500
	Sodium Carboxymethyl	1.000	1.000
	cellulose		
10	Sodium Saccharin	0.200	0.200
	Sodium Monofluorophosphate	0.760	0.760
	Sodium Diacid Orthophosphate	0.250	0.250
	monohydrate		
15	Deionized water-irradiated	19.700	19.700
	Alpha-alumina trihydrate	52.000	52.000
	(C-333)		
	Sodium lauryl sulphate	1.200	1.200
	Flavour	0.890	0.890
20	Coconut oil	<u>0.200</u>	<u>0.500</u>
	pH	7.1	7.0
		<u>1C</u>	<u>1D</u>
25	Glycerine	8.000	8.000
	Sorbitol (70%)	15.000	16.000
	Sodium Carboxymethyl	1.000	1.000
	cellulose		
	Sodium Saccharin	0.200	0.200
30	Sodium Monofluorophosphate	0.760	0.760
	Sodium Diacid Orthophosphate	0.250	0.250
	monohydrate		
	Deionized water-irradiated	19.700	19.700
	Alpha-alumina trihydrate	52.000	52.000
	(C-333)		

	Sodium lauryl sulphate	1.200	1.200
	Flavour	0.890	0.890
5	Coconut oil	<u>1.000</u>	<u>--</u>
	pH	6.91	7.0

After aging for at least 13 weeks at 25°C, the dental creams of Examples 1B and 1C remain creamy in consistency in laminate tubes of each laminate structure A and A-1 with no observed syneresis and the dental cream of Example 1A undergoes only slight syneresis while the dental cream of example 1D separates into liquid and solid phases within 1 week at 25°C in both of tubes of structures A and A-1.

EXAMPLES 2A TO 2D

The dental creams of Examples 1A to 1D are incorporated into a mechanical dispenser in accordance with US Patent 4,437,591 composed of polypropylene housing. The dental creams of Examples 1A, 1B and 1C retain their creamy consistency with little or no syneresis while the dentifrice of Example 1D separates into liquid and solid phases.

EXAMPLE 3

Similar results with respect to phase separation to those described above for Examples 1 and 2 are observed when:

- i. the relative amounts of glycerine and sorbitol (70%) are 6:24 and 18:6 and
- ii. each of palm oil, peanut oil and safflower oil are used in place of coconut oil;
- iii. the dental creams are packed in lamiated

- tubes in accordance with US Patent 3,260,410;
- iv. the dental creams are packed in crack-resistant laminated tubes in accordance with US Patent 4,418,841;
- v. The dental creams are packed in flexible sachets of the following structure from outermost to innermost layer:
- 12.2 microns polyethylene terephthalate
- 21.3 microns white ethylene acrylic acid
- 9.0 microns foil
- 3.3 microns ethylene acrylic acid
- 25.4 microns medium density polyethylene;
- vi. Mixture of 0.3 parts of sodium carboxymethyl-cellulose and 0.6 parts of xanthan replace sodium carboxymethyl cellulose as the sole gelling material;
- vii. 3.000 parts of calcined alumina replace 3.000 parts of alpha-alumina trihydrate; and
- viii. 10 parts of insoluble sodium metaphosphate replace 10.000 parts of alpha-alumina trihydrate;
- ix. sodium cyclamate replaces sodium saccharin.

EXAMPLES 4A AND 4B

The following dental creams having the compositions set out in Table 2 below are prepared to creamy consistencies and packed into tubes each of laminated structures A and A-1 set forth above:

Table 2

5	Example	<u>Parts</u>	
		<u>4A</u>	<u>4B</u>
	<u>Ingredient</u>		
	Glycerine	10.00	10.00
	Sodium Monofluorophosphate	0.76	0.76
	Sodium Benzoate	0.50	0.50
10	Sodium Carboxymethyl cellulose	0.95	0.95
	Tetrasodium Pyrophosphate	0.25	0.25
	Sodium Saccharin	0.20	0.20
	Sorbitol (70% solution)	17.00	18.00
	Coconut oil	1.00	----
15	Deionized water -irradiated	18.49	18.49
	Dicalcium phosphate dihydrate	48.76	48.76
	Flavour	0.89	0.89
	Sodium lauryl sulphate	1.20	1.20

20 After aging for 6 weeks at 25°C the dental cream of Example 4A remains creamy in consistency in each of the laminate tubes of structures A and A-1, while the dental cream of Example 4B separates into liquid and solid phases within 3 weeks at 25°C in both tubes of

25 structures A and A-1.

EXAMPLE 5

30 The dental creams of Examples 4A and 4B are incorporated into a mechanical dispenser in accordance with US Patent 4,437,591 composed of polypropylene housing. The dental cream of Example 4A retains its creamy consistencies while the dental cream of Example 4B separates into liquid and solid phases.

EXAMPLE 6

Similar results to those described above are observed when:

- i. calcium carbonate replaces dicalcium phosphate dihydrate;
- ii. dimagnesium phosphate trihydrate replaces dicalcium phosphate dihydrate;
- iii. the comparative amounts of glycerine and sorbitol (70%) are 6:24; and 18:6;
- iv. coconut oil is replaced by each of palm oil, peanut oil and safflower oil;
- v. the dental creams are packed in laminated tubes in accordance with US Patent 3,260,410;
- vi. the dental creams are packed in crack-resistant laminated tubes in accordance with US Patent 4,418,841;
- vii. the dental creams are packed in flexible sachets of the following structure from outermost to innermost layer;
12.2 microns polyethylene terephthalate
21.3 microns white ethylene acrylic acid
9.0 microns foil
3.3 microns ethylene acrylic acid
25.4 microns medium density polyethylene;
- viii. Sodium cyclamate replaces sodium saccharin.

It is understood that the foregoing details description is given merely by way of illustration and that variations may be made therein.



CLAIMS

1. A packaged stabilized dental cream packaged in a container, the inner resin surface of which is polyolefin, the said stabilized dental cream comprising at least about 20% by weight of a liquid vehicle comprising water, glycerine, sorbitol and a vegetable oil, the weight ratio of glycerine to sorbitol being from about 0.25:1 to about 3:1 and the amount of the said vegetable oil being about 0.1-5%, by weight, a solid vehicle comprising about 0.05-10% by weight of gelling agent, about 20-75% by weight of a dentally acceptable water-insoluble polishing material, at least a major portion of which is a water-insoluble alkaline earth metal salt or is alpha-alumina trihydrate, and when alpha-alumina trihydrate is present as the major portion of the polishing material, there is present a water-soluble material to reduce the pH of the dental cream to about 6-8 which provides phosphate ion.

2. A packaged stabilized dental cream as claimed in Claim 1 in which the weight ratio of glycerine to sorbitol is from about 0.25:1 to about 0.8:1.

3. A packaged stabilized dental cream as claimed in Claim 2 in which the weight ratio of glycerine to sorbitol is from about 0.6:1 to about 0.8:1.

4. A packaged stabilized dental cream as claimed in Claim 1, 2 or 3 in which the said vegetable oil is



present in an amount of about 0.5-2% by weight.

5. A packaged stabilized dental cream as claimed in Claim 1, 2, 3 or 4 in which the said vegetable oil is selected from the group consisting of coconut oil, palm oil, peanut oil and safflower oil.

6. A packaged stabilized dental cream as claimed in Claim 5 in which the said vegetable oil is coconut oil.

7. A packaged stabilized dental cream as claimed in any one of Claims 1 to 6 in which the said alpha-alumina trihydrate is the sole polishing agent present.

8. A packaged stabilized dental cream as claimed in any one of Claims 1 to 7 in which the said material which reduces the pH is inorganic.

9. A packaged stabilized dental cream as claimed in Claim 8 in which the said inorganic material which reduces the pH provides orthophosphate ion.

10. A packaged dental cream as claimed in Claim 9 in which the said material containing orthophosphate ion is selected from the group consisting of orthophosphoric acid, alkali metal diacid orthophosphate, ammonium diacid orthophosphate, alkali metal monoacid orthophosphate and ammonium monoacid orthophosphate.



11. A packaged stabilized material as claimed in Claim 10 in which the said material containing orthophosphate ion is a sodium diacid orthophosphate.

12. A packaged stabilized material as claimed in Claim 11 in which the said sodium diacid orthophosphate is sodium diacid orthophosphate monohydrate.

13. A packaged stabilized dental cream as claimed in any one of Claims 1 to 12 in which the said dental cream is packaged in direct contact with a polyolefin resin package surface.

14. A packaged dental cream as claimed in any one of Claims 1 to 13 in which the insoluble alkaline earth metal salt is present and is a calcium salt.

15. A packaged dental cream as claimed in Claim 14 in which the calcium salt is dicalcium phosphate dihydrate.

16. A packaged dental cream as claimed in Claim 1 substantially as specifically described herein with reference to Examples 1A, 1B or 1C and Example 3 or Example 4A or Example 6.

17. A packaged dental cream as claimed in any one of Claims 1 to 16 in which the container is a plastic laminate tube.

19. A packaged dental cream as claimed in Claim 18 in which the said polyethylene is low density polyethylene.

20. A packaged dental cream as claimed in any one of Claims 1 to 16 in which the container is a mechanical dispenser having a housing of polyolefin resin.

21. A packaged dental cream as claimed in Claim 20 in which the said polyolefin resin of the said housing is polypropylene.

22. A packaged dental cream as claimed in any one of Claims 1 to 16 in which the container is a flexible sachet.

23. A packaged dental cream as claimed in Claim 22 in which the inner polyolefin resin surface of the said sachet is low density polyethylene or medium density polyethylene.

24. A packaged dental cream as claimed in Claim 1 substantially as specifically described with reference to the accompanying Examples.