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(54) Title: A NON-FREEZING DENTIFRICE COMPOSITION

(57) Abstract: The present invention relates to a dentifrice composition comprising Polyethyleneglycol that is capable of providing relatively high warming effect during brushing while keeping the composition stable and does not allow it to solidify below sub-zero temperatures; and allowing the water-soluble actives present in the composition solubilised. The composition includes a selective combination of 50 to 65 weight% Polyethyleneglycol (or a derivative thereof), 2.5 to 15 weight% Glycerine and 5 to 7 weight% water.

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A NON-FREEZING DENTIFRICE COMPOSITION

FIELD OF INVENTION

The present invention relates to dentifrice compositions.

BACKGROUND AND RELATED ART

Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of the common general knowledge in the field.

Self-heating dentifrices are known in the art. Two types of heating or warming agents are generally included in dentifrices. They are thermal warming agents, and chemo-warming agents. Thermal-warming agents are heat-generating substances, i.e. exothermic agents, (e.g. those which generate heat upon hydration). Consumer satisfaction with a product is likely to be high if some type of sensory signal exists to remind the consumer that the product is working; and it is inter-alia for this reason that warming agents are included in oral-care compositions; more particularly in dentifrices. Some known thermal warming agents are synthetic Zeolites, Sodium carbonate, Calcium chloride, Magnesium sulphate, and Polyols such as Polyethyleneglycol (commonly and hereinafter referred to as PEG), Glycerol and Sorbitol. On the other hand, chemo-warming agents include Vanillin and related compounds, Pepper extract, Capsicum extract and Zingiber extract.

Dentifrices having a combination of two warming agents are also known in the art. WO1997/049374 (Henkel KGAA) discloses heating toothpastes having 20-85 weight% polyol of the Ethylene glycol, Propylene glycol or Glycerine group and 1-20 weight% of a dehydrated salt selected from Magnesium sulphate, Magnesium chloride or Calcium chloride.

Thus, it may be seen that the prior art is replete with disclosures of PEG and other polyols being used as thermal warming agents, particularly in toothpastes.

The present inventors have observed that amongst the known thermal-warming agents; liquid, low molecular weight Polyethyleneglycol, having molecular weight in the range of 200 to 600 g/mol provides desirable degree of initial warmth during brushing. However, it was also observed by the present inventors that when high amount of PEG is used in the composition, it lead to solidification of the composition, especially at lower temperatures. On the other hand, regulatory laws of certain countries such as China, dictate that when the dentifrice compositions are stored at -8 °C for 8 hours; at least 1-2 mm paste should come out of the tube at a squeeze pressure less than or equal to 40 kPa. This means that the composition should not solidify below sub-zero temperatures. A further problem identified by the present inventors is that while using PEG, if the amount of water in the composition is not properly controlled, then either the water-soluble actives such as Zinc sulphate and Sodium fluoride, which are usually present in the compositions are poorly solubilised, or if too much water is included, then a large part of PEG gets hydrated in the container (tube) itself, which in effect reduces the amount of active material responsible for warming sensation by de-activating it before actual use.

Thus, there exists an un-met need for a solution for the above-mentioned problems.

The present inventors have surprisingly found that the above-mentioned problems can be solved when the dentifrice composition includes a selective combination of Polyethyleneglycol (or a derivative thereof), Glycerine and water.

OBJECT OF THE INVENTION

It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art.

It is an object of the present invention to provide a dentifrice composition comprising Polyethyleneglycol:

- which provides relatively high warming effect;

- which does not solidify below sub-zero temperatures; and,
- in which, the water-soluble actives present in the composition are solubilised.

Other objects of the present invention will become apparent to those skilled in the art by reference to the specification.

SUMMARY OF THE INVENTION

According to an aspect, the present invention provides a dentifrice composition comprising:

(i) 50 to 65 weight% Polyethyleneglycol, or a derivative thereof;
(ii) 2.5 to 15 weight% Glycerine; and,
(iii) 5 to 7 weight% water.

Preferably the molecular mass of Polyethyleneglycol is in the range of 400 to 600 g/mol.

The term “comprising” is meant not to be limiting to any subsequently stated elements but rather to encompass non-specified elements of major or minor functional importance.

In other words the listed steps, elements or options need not be exhaustive. Whenever the words “including” or “having” are used, these terms are meant to be equivalent to “comprising” as defined above.

Except in the operating and comparative examples, or where otherwise explicitly indicated, all numbers in this description indicating amounts of material ought to be understood as modified by the word “about”.

It should be noted that in specifying any range of concentration or amount, any particular upper concentration can be associated with any particular lower concentration or amount.

For a more complete understanding of the above and other features and advantages of the invention, reference should be made to the following detailed description of preferred embodiments.

DETAILED DESCRIPTION

The term "weight%" used throughout the specification means percentage by weight.

The term "PEG" and Polyethyleneglycol have been used inter-changeably in the specification.

In general, it is preferred that the degree of warming should be such that upon normal use of the dentifrice, the temperature of the dentifrice/saliva mixture and the resultant foam generated in the oral cavity reaches, within 30 seconds, for example, a value of 37 to 39 °C. Too high a temperature should be avoided as this may cause an unpleasant sensation in the mouth. Preferably the difference between the initial temperature and the increased temperature should be no more than 5 °C, and more preferably should be in the range of 0.4 to 2 °C. The present inventors have found that by the choice of the amount of Polyethyleneglycol, or the derivative thereof; the degree of warming in the oral cavity can be controlled. The amount of Polyethyleneglycol or the derivative thereof is in the range of 50 to 65 weight%, more preferably in the range of 50 to 56 weight%. It is to be noted that if the dentifrice contains optional ingredients which absorb heat upon hydration or solution; the amount of PEG or the derivative thereof will be at the higher end of these ranges to compensate for this heat absorbed and to still provide the self-heating effect.

The molecular mass of Polyethyleneglycol is in the range of 200 to 600 g/mol, more preferably in the range of 300 to 600 g/mol. It is particularly preferred that the molecular mass is in the range of 400 to 600 g/mol. It has been observed that PEG having molecular mass 600 g/mol is the least bitter of all. Instead of, or in addition to PEG, the composition may include a derivative thereof. A preferred derivative of Polyethyleneglycol is Polyethyleneglycol mono methyl ether, further preferably having

molecular mass 550 g/mol. A combination of PEG of different molecular masses in the abovementioned range, or a combination of PEG and a derivative of PEG may also advantageously be used.

The dentifrice composition includes 2.5 to 15 weight% Glycerine, which serves as a humectant. Preferred level of Glycerine is in the range of 8 to 10 weight%.

The dentifrice composition must be low in water, which means that it preferably contains 5 to 7 weight% water, more preferably 7% free water, which limit is exclusive of any free water present in the ingredients of the dentifrice.

It is preferred that the composition includes 0.1 to 0.5 weight% binder selected from Carrageenan or Sodium carboxy methyl Cellulose. It is further preferred that the composition includes 0.1 to 0.4 weight% Sodium carboxy methyl Cellulose (hereinafter referred to as SCMC), as the binder. SCMC is particularly preferred as it gives desired viscosity profile at relatively lower usage level. A combination of Carrageenan and SCMC is also particularly preferred. Synthetic polymers such as polyacrylates and carboxyvinyl polymers such as CARBOPOL™ may also be used.

The viscosity of the dentifrice composition preferably is in the range of 160000 to 300000 cP, more preferably in the range of 180000 to 300000 cP, and most preferably in the range of 180000 to 220000 cP. The viscosity is measured at 25 °C with a BROOKFIELD™ Viscometer using T-bar D-spindle at 5 rpm.

While the composition can be in the form of an opaque chalk/silica based toothpaste or a transparent gel; it is preferred that the dentifrice composition is a gel, as gel-based dentifrices have higher consumer appeal and acceptance. The composition may also be a suitable combination of a paste and a gel in the form of dual-compositions, available generally in core-&-sheath, deep-stripe and co-extruded formats.

The balance of the dentifrice composition of the invention preferably includes conventional dentifrice ingredients. Such ingredients include cosmetically acceptable carriers like alcohol systems. Small amounts of surfactants, such as anionic, non-ionic or amphoteric surfactants may also be included. Other ingredients may be particulate abrasive materials including agglomerated particulate abrasive materials such as silicas, aluminas, calcium carbonates (both natural and synthetic), di-calcium phosphates, calcium pyrophosphates, hydroxyapatites, trimetaphosphates, and insoluble hexametaphosphates, usually in amounts between 5 to 60 weight%.

Flavours such as peppermint and spearmint oils may also preferably be included. It is also preferred to use preservatives, opacifying agents, colouring agents, pH-adjusting agents and sweetening agents.

It is particularly preferred that the dentifrice composition contains an anti-bacterial agent selected from Copper, Zinc or Stannous salts such as Zinc citrate, Zinc sulphate, Sodium Zinc citrate and Stannous pyrophosphate. Further examples of anti-bacterial agents which may be included are quaternary ammonium compounds such as cetylpyridinium chloride; bis-biguanides such as chlorhexidine, chlorhexidine digluconate, hexetidine, octenidine, alexidine; TRICLOSAN™ and other halogenated bisphenolic compounds such as 2,2' methylenebis-(4-chloro-6-bromophenol). A particularly preferred antibacterial agent is Zinc sulphate.

Further, the composition may also include antioxidants. Preferred antioxidants for use in dentifrice compositions are those that are compatible with other components of the composition and are not hazardous to health. Preferred antioxidants include ascorbic acid, erythorbic acid, ascorbyl palmitate, thiodipropionic acid, calcium ascorbate, dilauryldithiopropionate, gum guaiac, sodium ascorbate, Butylated hydroxyl Toluene, Butylated hydroxyl Anisole, and tocopherols. Mixtures and combinations of antioxidants can be used. If present, the antioxidant is added in a level effective to reduce or mitigate discoloration that would otherwise result from oxidation of the components of the dentifrice compositions. It is preferred that the levels range from about 0.01 to 1 weight%, based on the total weight of the dentifrice composition.

Polymeric compounds which can enhance the delivery of active ingredients such as anti-bacterial agents can also be included. Examples of such polymers are copolymers of polyvinylmethylether with maleic anhydride and other similar delivery enhancing polymers.

Anti-caries agents such as sodium- and stannous fluoride, aminefluorides, monosodiumfluorophosphate, casein, plaque buffers such as urea, pyruvates, arginine, small peptides, and calcium glycerophosphate may also be included. It is particularly preferred that the anticaries agent is Sodium fluoride. The addition of the fluoride containing agent will preferably be at such an amount to provide free fluoride ion at from 100 to 2000 ppm, preferably from 900 to 1500 ppm.

Other optional ingredients include vitamins such as Vitamin C; and plant extracts. Desensitising agents such as potassium tartrate, potassium citrate, potassium chloride, potassium bicarbonate, potassium oxalate, potassium nitrate, calcium phosphates as well as strontium salts, bleaching agents such as peroxy compounds e.g. sodium percarbonate, potassium peroxydiphosphate, effervescing systems such as sodium bicarbonate/citric acid systems, colour change systems, anti-bad breath ingredients may also be included. The composition may also include one or more of breath strips, sparkles, large silica particles, granules, beads, and flavour encapsulates for enhanced sensory benefits or for visual appeal.

Buffers and salts to buffer the pH and ionic strength of the compositions may also be included.

The heating effect provided by the dentifrice composition according to the invention is generally linked to the efficacy of the product by the consumers.

Further details of the invention, its objects and advantages are explained hereunder in greater details with reference to the following non-limiting examples. It would be apparent to a person skilled in the art that many such examples are possible and the examples given under are for illustrative purpose only. These should not be construed so as to limit the scope of this invention in any manner.

EXAMPLES

EXAMPLE-1

A gel dentifrice composition (Composition-A) having the formulation as given in Table-1 below was prepared by the procedure as given in Example-2 below.

Table-1

Ingredients/weight%	Composition-A
PEG molecular mass 600 g/mol (PEG-600)	56.0
Glycerine	10.0
Water	7.0
Hydrated silica	23.0
SCMC	0.4
Sweetener	0.5
Sodium fluoride	0.2
Zinc Sulphate	0.2
Sodium Lauryl Sulphate	2.0
Colourants, pigments, flavour and other minors to	100

EXAMPLE-2

Method of preparation of Composition-A

The method of preparation involved two stages:

Stage-1: Pre-hydration of SCMC

Glycerine and SCMC were separately weighed. SCMC was then gradually added to Glycerine under stirring at room temperature, while ensuring that no lumps were formed, and the powder completely dispersed into the liquid phase giving a clear viscous dispersion. Stirring was discontinued after the addition of SCMC was complete. The resultant clear dispersion was checked for the presence of any un-dissolved matter before proceeding further. This premix was added to pre-weighed water under stirring, until the addition was completed and the mixture was completely homogenized. This pre-hydrated mix was used for preparation of gel-based toothpaste as per the procedure in stage-2. Pre-hydration stage takes about 25 to 30 minutes.

Stage-2: Preparation of the dentifrice composition

All of the PEG-600 was charged into a FRYMA™ Mixer. To this mixer, Sodium fluoride and Zinc sulphate were added. The scraper of the mixer was started and the contents of the mixer were mixed under vacuum for about 5 to 10 minutes. Next, part of hydrated silica (10 g) was added and the contents were mixed for further 10 minutes. To this mixture, the pre-hydrated binder mix as prepared in Stage-1 above was added while maintaining the mixer under vacuum for about 5 minutes. Next, the remaining part of hydrated silica was added and the mixture was further mixed for about 5 minutes. Finally the colourant, pigment, other minors, sweetener and Sodium Lauryl Sulphate were added to the mixer, and the mixture was further mixed for another 10 minutes. At the end, the mixture was cooled below 38 °C and the flavour was added. The preparation was further mixed under vacuum for about 10 minutes to obtain the final dentifrice composition in gel form.

Example-3

Dentifrice compositions including PEG-400 and PEG monomethyl ether-550

In another experiment, two gel toothpaste compositions; one containing PEG-400 and the other containing PEG mono methyl ether-550 with their respective formulations as given in Table-2 below were made by the method as given in Example-2 above. In the method, PEG-400 and PEG mono methyl ether-550 were used instead of PEG-600.

Table-2

Ingredient/weight%	Composition B	Composition C
PEG-400	56.0	--
PEG mono methyl ether-550	--	56.0
Glycerine	10.0	10.0
SCMC	0.4	0.4
Water	7.0	7.0
Hydrated silica	23.0	23.0
Sodium Lauryl Sulphate	2.0	2.0
Sweetener	0.2	0.2
Sodium fluoride	0.2	0.2
Zinc Sulphate	0.2	0.2
Colourants, pigments, flavour and other minors to	100	100
Increase in temperature by	2 to 3 °C	2 to 3 °C

Next 1 g of the composition at 22.7 °C was mixed with 1 g water at 37 °C to observe the increase in temperature, which was recorded for both the compositions. These results have also been included in Table-2.

The results in the table above indicate that those compositions which had PEG-400 or PEG mono methyl ether-550 also showed appreciable rise in temperature.

EXAMPLE-4

Experiments on solidification of compositions within the invention at sub-zero temperature

In this experiment, a series of dentifrice compositions containing a combination of Polyethyleneglycols of various molecular masses (all within the scope of the present invention) were made by the method as given in Example-2. The compositions of the dentifrices are given in Table-3 below.

Table-3

Ingredient/ weight%	Compositions		
	D	E	F
Glycerine	10.0	10.0	10.0
SCMC	0.4	0.4	0.4
Water	7.0	7.0	7.0
PEG-600	5.5	3.0	0
PEG-400	0	5.2	11.0
PEG-300	50.3	47.6	44.8
Hydrated silica	23.0	23.0	23.0
Sodium Lauryl Sulphate	2.0	2.0	2.0
Sweetener	0.5	0.5	0.5
Sodium fluoride	0.2	0.2	0.2
Zinc sulphate	0.2	0.2	0.2
Colour, Pigments flavour and other minors to	100	100	100

The compositions were then filled in standard collapsible tubes and the tubes were immersed in ice maintained at -9 °C, for 30 minutes. After this, it was checked whether the tubes could be manually squeezed or not, and whether the compositions had solidified inside the tubes or not. Next, 1 g of each of the compositions at 22.7 °C was mixed with 1 g water at 37 °C to observe the increase in temperature. The increase in temperature was recorded for all the compositions. The results have been shown in Table-4 below.

Table-4

Composition	**D**	**E**	**F**
Solidification of the composition	Did not solidify at -9°C	Did not solidify at -9 °C	Did not solidify at -9 °C
Squeeze-ability of the tube	squeezable at -9°C	squeezable at -9°C	squeezable at -9°C
Recorded temperature rise in °C	0.7	1.5	0.4

The data in the above table indicates that a combination of Polyethyleneglycols of different molecular masses provide dentifrice compositions which did not solidify at -9°C, which is an important property to meet the Regulatory requirements of countries such as China. The data also indicates that the dentifrices showed an appreciable rise in temperature.

EXAMPLE-5

Effect of binder on the viscosity of the composition

In another set of experiments, the effect of various binders on the viscosity of the compositions was studied by preparing three compositions, in which the formulations were similar to that of Composition-A in Table-1, except for the change in the binders.

Details of the variations in the individual compositions are given in Table-5 below. The formulation of the three compositions G, H and I were similar to that of Composition-A in Table-1, except for the replacement of the binder. In case of Composition-I, an equivalent amount of water was reduced from Composition-A, as the amount of binder in Composition-I was 0.5 weight%, as against 0.4 weight% in Composition-A. Further, viscosity of all the compositions was measured after storing them at 25 °C and 50% Relative humidity for 14 days. The viscosity was measured at 25 °C with a BROOKFIELD™ Viscometer using T-bar D-spindle at 5 rpm. This data is also included in Table-5 below.

Table-5

Composition	Binder	Weight%	Viscosity/(cP)
A (of Table-1)	SCMC	0.40	218000
G	Carrageenan	0.40	161000
H	Xanthan gum	0.40	69000
I	Carrageenan and SCMC	0.50 (0.25 weight% each)	270000

Thus it can be seen that Composition-A, Composition-G, and Composition-I had viscosity in the range of 160000 to 300000 cP, which provides for relatively higher physical stability. This viscosity allows for a relatively smoother extrusion of the dentifrice composition from a tube. On the other hand, Composition-H had viscosity outside the above range.

EXAMPLE-6

Squeeze pressure test of the compositions within the invention

In this experiment, four dentifrice compositions containing a combination of Polyethyleneglycols of various molecular masses (all within the scope of the present invention) were made as per the method given in Example-2. The compositions were then filled in standard collapsible tubes. The filled tubes were then subjected to squeeze pressure test, as follows:

Procedure for determining squeeze pressure

Requirements

1. Icebox at -8 °C, resolution 1 °C
2. Chinese Squeeze Pressure Test Instrument (including a compressor).
3. Standard cap of collapsible tubes.

Two samples of the compositions filled in standard collapsible tubes were put into an ice box maintained at

-8 °C for 8 hours. Before the test, the first 20 mm ribbon of the composition was squeezed out of the tube and discarded. The tubes were then capped with a standard cap and put onto a Chinese Squeeze Pressure Test Instrument. The compressor of the instrument was started and the pressure at the point where 1-2 mm paste was squeezed out of the tube was recorded. Thereafter, the compressor was closed and the vent was opened to let the pressure go back to zero. The dentifrice composition was removed, the vent was closed and the compressor was started again to repeat the test with the same sample. The maximum pressure at the point where 1-2 mm paste was squeezed out of the tube was recorded. The same test was repeated for

the second sample. The final pressure value was recorded as the mean of the 4 recorded values (2 values for each sample)

Details of the compositions and the results of the squeeze pressure test performed on the composition are provided in Table-6 below.

Table-6

Ingredient/weight%	**Composition**			
	J	**K**	**L**	**M**
Glycerine	10.0	10.0	10.0	10.0
SCMC	0.4	0.4	0.4	0.4
Water	7.0	7.0	7.0	7.0
PEG-600	18.0	14.0	10.0	8.0
PEG-400	-	42.0	46.0	48.0
PEG-300	38.0	-	-	-
Hydrated silica	23.0	23.0	23.0	23.0
Sodium Lauryl Sulphate	2.0	2	2.0	2.0
Sweetener	0.2	0.2	0.2	0.2
Sodium fluoride	0.2	0.2	0.2	0.2
Zinc sulphate	0.2	0.2	0.2	0.2
Colour, Pigments flavour and other minors to	100	100	100	100
Squeeze Pressure/ kPa	**35**	**24**	**23**	**20**

The data in the above table indicates that a combination of Polyethyleneglycols of different molecular masses provide dentifrice compositions for which the Squeeze-Pressure values were less than 40 kPa.

It will be appreciated that the illustrated examples provide a dentifrice composition present invention to provide a dentifrice composition comprising Polyethyleneglycol:

- which provides relatively high warming effect;
- which does not solidify below sub-zero temperatures; and,
- in which, the water-soluble actives present in the composition are solubilised.

It should be understood that the specific forms of the invention herein illustrated and described are intended to be representative, only as certain changes may be made therein without departing from the clear teachings of the disclosure.

Although the invention has been described with reference to specific embodiments, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms.

Claims

1. A dentifrice composition comprising:
   (i) 50 to 65 weight% Polyethyleneglycol or a derivative thereof;
   (ii) 2.5 to 15 weight% Glycerine; and
   (iii) 5 to 7 weight% water.

2. A dentifrice composition as claimed in claim 1 wherein the molecular mass of said Polyethyleneglycol is in the range of 300 to 600 g/mol.

3. A dentifrice composition as claimed in claim 1 or 2 wherein said Polyethyleneglycol or derivative thereof is in the range of 50 to 56 weight%.

4. A dentifrice composition as claimed in any one of the preceding claims wherein said Glycerine is in the range of 8 to 10 weight%.

5. A dentifrice composition as claimed in any one of the preceding claims comprising 0.1 to 0.5 weight% binder selected from Carrageenan or Sodium Carboxy Methyl Cellulose.

6. A dentifrice composition as claimed in any one of the preceding claims wherein viscosity of said composition is in the range of 160000 to 300000 cP.

7. A dentifrice composition as claimed in any one of the preceding claims 2 to 6 wherein said molecular mass of Polyethyleneglycol is in the range of 400 to 600 g/mol.

8. A dentifrice composition as claimed in any one of the preceding claims wherein said derivative of Polyethyleneglycol is Polyethyeleneglcyol mono methyl ether.

9. A dentifrice composition substantially as herein described with reference to the accompanying examples.