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(54) Title: MULTIPHASE TOOTHPASTE COMPOSITION

(57) Abstract: A multiphase toothpaste comprising an opaque phase and a transparent gel phase, each said phase having a mobile phase with an effective amount of cleansing or polishing agents suspended therein, and wherein of the ingredients making up more than 2% of each mobile phase a corresponding amount of said ingredients is present in the other mobile phase such that no substantial transfer of ingredients occurs between the mobile phases.



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MULTIPHASE TOOTHPASTE COMPOSITION

The present invention relates to multiphase toothpaste and in particular to multi phase stable toothpaste comprising combinations of transparent gel phase and non-transparent opaque phase with good cleansing, polishing and freshening properties.

Multiple toothpastes involving gel (transparent) and opaque (non-transparent) phases are commercially attractive and are mostly directed to add to the consumer appeal of the product.

GB 1271944 discloses toothpaste comprising a main body which is a transparent or translucent gel and a secondary body of cleaning and polishing agents contained at least partially within the main body. However, such multi-phase commercially attractive toothpastes have certain disadvantages in terms of tooth cleaning or tooth polishing properties. As would be apparent from the patent while the toothpaste proposed involved a main gel body which served the aesthetic purpose, the same was found not good for cleaning and polishing as the main gel body had to be free of cleansing /polishing agents which were found to affect the transparent character of the gel. Therefore, the toothpaste while meeting the aesthetic demands of the multi-phase toothpaste had limitations in terms of effective cleaning and polishing properties due to limitations in incorporation of cleaning and polishing agents in the major gel phase.

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EP Application 0076563 suggests another multiphase toothpaste directed to improve the cleaning and polishing properties consisting of an opaque white paste matrix as the main body containing required cleaning and polishing agents and the gel phase constituting the minor secondary body. 5 Notably in this EP '563 the arrangement of the multiphase toothpaste proposed is just the reverse of the combination suggested in GB 1271944 to achieve better cleaning or polishing by suggesting a main opaque body which could 10 contain higher amounts of the cleaning and polishing agents and a minor secondary gel phase which had limitations in incorporation of such cleaning and polishing agents.

It would be apparent from the above that although the above 15 EP multiphase formulation was directed to achieve better cleansing and polishing properties, the same essentially suggested a major opaque phase with higher levels of cleaning/polishing agents and proposed that substances which are normally incompatible with the secondary gel bodies such 20 as the dentally acceptable abrasives etc. be included in the opaque paste matrix.

Apart from the limitations of incorporating cleansing /polishing agents in the gel phase, the multiphase 25 toothpastes are found to further suffer from problems of stability, especially when dyes/color/mobile ingredients are incorporated, problem of bleeding i.e. diffusion/undesirable interaction between the gel and opaque phase take place with consequent loss of aesthetic value and appeal.

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To avoid such diffusion/undesirable interaction between the gel and opaque phase the EP' 563 further proposed matching of the pH values of the different phases.

5 US 4814160 on the other hand to avoid the problem of bleeding of the colouring material from the striped component into the white based component proposed substantially different two component dentifrice formulations. In particular the patent suggests a gel
10 component of organic pigment along with Xanthan gum as the sole gelling agent and a white component selected from Kappa-carrageenan mixture in distinctly different liquid vehicles containing different dentally acceptable polishing agents.

15 US 5989870 discloses yet another multi-phase dentifrice composition with a herb medicine extract - containing striped phase to avoid transfer of colorants at the interface from coloured component (stripes) to the base
20 component.

Prior art multi-phase toothpaste reveal that while consumer demand require such multi-phase toothpastes to add to the aesthetic and eye appeal of the toothpaste especially by use
25 of the gel and opaque phase combinations, there are limitations in achieving desired cleaning and polishing effects from such multi-phase formulations due to restriction in incorporation of polishing and cleaning agents in the gel phase and also limitations in obtaining
30 various eye appealing gel-opaque combinations due to need to restrict the gel phase as the minor/secondary phase to

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facilitate incorporation of the polishing/cleaning agents in the main opaque phase. Also, the above state-of-art reveals the problems of bleeding colour/dyes from the one phase into the other and need to have totally different formulations

5 for the gel and opaque phase to avoid such problem of difference and/or the use of selective herbal extract to control bleeding in multi-phase toothpaste.

It is thus the basic objective of the present invention to
10 provide for a multiphase toothpaste such as combinations of non-transparent opaque phases and transparent gel phases which would enable greater flexibility in selection/incorporation of actives/additives in the respective phases maintaining desired stability.

15

Another object of the present invention is to provide for a multiphase toothpaste involving combinations of non-transparent opaque phase and transparent gel phase which would avoid the above prior art limitations of incorporating
20 polishing and cleaning agent in the gel phase and thereby improve upon the cleaning and polishing properties of such multi-phase toothpastes.

Another object of the present invention is to provide a
25 stable multiphase toothpaste which on one hand would maintain the desired cleansing/polishing characteristics and on the other hand would avoid the limitation of restricting the gel phase (due to problems of incorporation of cleaning and polishing agents) as the secondary formulation of the
30 toothpaste and thereby provide for the desired flexibility

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in obtaining aesthetically appealing varied forms of multi-phase toothpaste with gel phase of about 50% v/v or more.

Yet another object of the invention is directed to deliver
5 superior freshness while achieving the desired
cleaning/polishing by providing abrasives in both the gel
and the opaque part of the toothpaste formulation.

Yet another object of the present invention is directed to a
10 cost effective multiphase toothpaste which would provide for
the desired flexibility in the levels and selection of
dental actives/abrasives in the respective phases and at the
same time impart desired independence to the respective
phases for effective functional, cleaning and polishing
15 properties.

Yet another object is directed to a two phase gel-opaque
phase side by side disposed toothpaste which would serve the
much desired aesthetic and consumer appealing purposes of a
20 multiphase toothpaste and yet achieve superior
cleansing/polishing characteristics without requiring a main
(more than 60 % v/v) opaque body.

Yet further object of the present invention is directed to
25 the development of a multiphase toothpaste, involving a gel
phase which can be obtained of commercial toothpaste
actives/ingredients and yet be of desired stability and
avoid problems of diffusion/migration of mobile components
between the phases and resulting contamination/loss of
30 desired aesthetic appeal of the toothpaste on storage.

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Thus according to the basic aspect of the present invention there is provided a multiphase toothpaste according to claim 1.

5 In the above multi-phase toothpaste composition of the invention the mobile phase in each of said gel and opaque phases comprises of its liquid contents together with its soluble ingredients.

10 For the sake of clarity, those mobile phase ingredients comprising more than 2% of the mobile phase will be denoted by the term major mobile phase ingredients.

The term transparent in this invention refers to
15 compositions which have a desired transmittance of light passing through a sample of the composition as measured by the technique mentioned below. The transmittance of a sample is measured in a $\frac{1}{4}$ " cell on a Shimadzu 1601 spectrophotometer modified to mount a $\frac{1}{4}$ " cell. The light
20 used is one of wavelength 400-800 nm. The transmittance of the sample is measured against a reference which is distilled water. Samples having transmittance greater than 1, preferably greater than 2, more preferably greater than 5 and further more preferably greater than 10 are termed
25 transparent. Translucent samples measured using the above technique have a transmittance less than 1.

It is particularly preferred that the major mobile phase ingredients of the mobile phase of each of the said
30 opaque/gel phases of the multiphase combination do not differ substantially, i.e. they are balanced such that

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substantially no transfer occurs between phases in the final product.

Thus the mobile phase can comprise of liquids selected from
5 conventional liquid ingredients selected from humectants, foaming agents, flavours, polymers, and water.

Also, the soluble ingredients in the mobile phase can include sweeteners, humectants, structurants, binders,
10 buffering agents, foaming agents, preservatives, and dental actives.

The mobile phases of the gel and opaque phases range from 20 to 95 % w/w preferably 30 to 90% w/w.

15

Importantly, due to the above selective substantial matching of the concentration of the major mobile phase ingredients in the gel phase and the opaque phase in the multiphase formulation of the invention, it is now possible to on one
20 hand achieve multi-phase formulations including gel phase which could include abrasives and other cleaning and /or polishing agents and thereby add on to the cleansing and polishing effects of gel phase apart from the cleaning/polishing achieved by the opaque phase. The gel
25 phase which earlier basically served the aesthetic purpose only and was thus preferred only as the minor secondary body can now by way of the selective multi-phase formulation of the invention apart from serving the aesthetic purpose would also provide the desired cleansing and polishing activity
30 thereby improve the cleansing/polishing activity of such multiphase toothpastes.

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In accordance with the above the gel phase in the formulation of the invention comprises by weight of the gel phase, abrasives from 4-40% by wt., humectants 1-90%, sweetening agents 0-2%, foaming agents 0-5%, thickening agents 0-20%, binders 0.1-25% and balance water. Gel phase can also contain dental actives and flavour compounds for freshness delivery at the efficacious levels.

The opaque phase comprises of, by weight of the opaque phase, of abrasives from 4 -70%, humectants 1-90%, sweetening agents 0-2, foaming agents 0- 5%, thickening agents 0-20%, binders 0.1-25% and balance water. The opaque phase can also contain dental actives at efficacious levels.

The thickening agents, dyes, preservatives and flavours etc. can be added depending upon the product specification.

The content of the mobile phase in each of said gel/opaque phases can preferably include: humectants from 1 to 90%, binders from 0.1 to 40, foaming agents from 0 to 5 %, flavours from 0 to 2%, buffering agents from 0 to 5 %, actives:qs, water to 100.

The abrasives can be selected from chalk, silica or other known abrasives and their combinations. Suitable binders include sodium carboxy methyl cellulose, carrageenans, xanthan gum, guar gum, polymers and combination thereof.

In accordance with a preferred aspect of the present invention there is provided a multiphase toothpaste comprising two side by side transparent-gel and opaque

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phases, said transparent-gel phase comprising 40 to 60% v/v preferably 44 to 50 % and said opaque phase comprising 40 to 60% v/v preferably 50 to 56 % and wherein each said phase have effective amount of cleansing/polishing agents and comprising of a mobile phase and selected such that the major mobile phase ingredients of said mobile phase of each of said opaque/gel phases of the multiphase combination do not differ by more than 50% across the different opaque/gel phases.

It is thus possible to obtain varied combinations/arrangements of gel-opaque phases with desired stability and cleansing/polishing property and desired functional efficacy.

In accordance with another aspect of the invention, the multiphase toothpaste comprises a gel phase which is at least partially within the opaque phase.

It is thus possible in such case to obtain said one phase in the form of core or cores surrounded by the other phase and the phases can be chosen from opaque phase or transparent gel phase. Alternatively, the gel phase can comprise of stripe or stripes partially contained within the opaque phase with a portion of the surface of the stripe exposed at the surface of the main body.

Importantly, in the above disclosed multiphase toothpaste of the invention, the toothpaste formulation on one hand achieves the desired maintenance of two or more phases in its stable condition even upon storage and on the other hand

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apart from serving the aesthetic purpose of multiphase toothpaste the same does not suffer from the limitation of insufficient cleansing and polishing properties of some of the phases especially the gel phase. In other words, each
5 of the phases of the multiphase toothpaste of the invention be it the gel phase or the opaque phase are self sufficient to serve as effective cleansing and polishing media thereby providing for the desired cleansing and polishing effect in use of such formulation.

10

Moreover by maintaining the mobile phase i.e. a liquid phase and its soluble ingredients of the respective phases matched or substantially the same it is possible to on one hand avoid problems of bleeding and/or discharge of
15 contents/ingredients from one phase to other and on the other hand facilitate maintaining each of the phases self sufficient as far as its cleaning and polishing properties are concerned in particular by providing for incorporation of abrasives.

20

Added to the above advantages, the above balancing of the mobile phase also provides flexibility in selection of the mobile phase and the insolubles therein in the respective phases with possible avoiding of cost-extensive liquids such
25 as humectants, flavours and replacement by cost-effective abrasives such as chalk. The invention is thus directed to provide cost-effective multiphase dentrifice formulation with superior cleansing/polishing properties.

30

It is also found that the above maintenance of the uniform liquid phase content of the respective phases make it

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possible to incorporate increased amounts of benefit agents such as abrasives required for effective cleansing and polishing without sacrificing the aesthetic appeal of such gel based formulations.

5

The process for manufacture of the multiphase toothpaste of the invention comprise conventional manufacture techniques of multi-phase toothpastes such as for obtaining the selective gel-opaque side-by-side combination, the two
10 phases are provided such that the two phases will coextrude in a side-by-side/sandwich format. For obtaining striped multiphase toothpaste the conventional striping technique and toothpaste dispensing device may be used.

15 The details of the invention its objects and advantages are explained hereunder in greater detail in relation to non-limiting exemplary illustrations.

EXAMPLES

20

Example 1

Under this example, the multiphase toothpaste of the invention was obtained comprising a 50:50 (v/v) opaque:gel
25 phase combination. The selective ingredients used in the respective phases are detailed hereunder in Table 1.

Importantly, the above selective ingredients for the gel phase and opaque phase in the multiphase (50:50) formulation are in accordance with the invention selected to have
30 substantially the same mobile phase concentrations. The mobile phase as used and intended in the formulation of the

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invention i.e. the liquid and soluble content of the respective phases common to both the gel and the opaque phase are as hereunder in Table-1:

5 **Table-1**

Opaque Phase

	% by weight of opaque phase	% by weight of mobile phase
70% Sorbitol solution (aq)	43.0	79.0
Poly ethylene glycol (PEG) 1500	1.3	2.4
Sodium lauryl sulphate (SLS)	1.8	3.2
Chalk	40.0	-
Thickener Silica	5.0	-
Water	5.8	10.6
Other minors	3.1	To 100

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Gel Phase

	% by weight of gel phase.	% by weight of mobile phase
70% Sorbitol solution	66.0	79.0
PEG 1500	2.0	2.4
SLS	2.7	3.2
Abrasive silica	8.0	-
Thickener silica	8.4	-
Water	8.8	10.6
Other Minors	4.1	To 100

The two phase formulation of the invention is compared with
5 an available conventional transparent gel formulation and a
conventional opaque formulation placed in a side by side
format as Comparative Example A, below.

Comparative Example A:

10

Under this example, a conventional gel and an opaque
toothpaste formulation were filled in a side by side format.
The gel and opaque phase content of this formulation were
such that the mobile phase was substantially different in
15 the two phases, as shown in Table 2 below.

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Table 2:Opaque Phase

	% by weight of opaque phase	% by weight of mobile phase
70% Sorbitol solution	15.0	27.3
Poly ethylene glycol (PEG) 1500	0	0
Sodium lauryl sulphate (SLS)	2.5	4.6
Chalk	40.0	-
Thickening silica	5.0	-
Water	32.8	59.8
Other minors	4.7	To 100

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Gel Phase

	% by weight of gel phase.	% by weight of mobile phase
70% Sorbitol solution	66.0	79.4
PEG 1500	2.0	2.4
SLS	2.8	3.4
Abrasive and thickening silica	16.9	-
Water	10.6	12.1
Other Minors	1.7	To 100

Example 2

- 5 Under this example, the multiphase toothpaste of the invention was obtained comprising a 50:50 (v/v) opaque:gel phase combination. The selective ingredients used in the respective phases are detailed hereunder in Table 3.
- 10 Importantly, the above selective ingredients for the gel phase and opaque phase in the multiphase (50:50) formulation are in accordance with the invention selected to have the major mobile phase ingredients of each of the said opaque/gel phases of the multiphase combination such that they do not differ by more than 35% across the different
- 15 opaque/gel phases. The composition of the opaque phase and the transparent gel phase and the mobile phase concentrations in each of those phases are given in Table 3:

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Table-3Opaque Phase

	% by weight of opaque phase	% by weight of mobile phase
70% Sorbitol solution	38.0	71.8
Poly ethylene glycol (PEG) 1500	1.3	2.5
Sodium lauryl sulphate (SLS)	2.0	3.8
Sodium silicate	1.8	3.4
Chalk	42.0	-
Abrasive Silica	4.6	-
Water	6.9	13.0
Other minors	3.4	To 100

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Gel Phase

	% by weight of gel phase.	% by weight of mobile phase
70% Sorbitol solution	65.0	77.2
PEG 1500	2.0	2.4
SLS	2.7	3.6
Sodium silicate	2.5	3.0
Abrasive silica	15.8	-
Water	8.5	10.0
Other Minors	3.5	To 100

The multiphase toothpaste samples of the invention (Examples 1 and 2) and comparative Example A were tested for stability in terms of transparency and other user properties like squeezability from a tube over time a period of storage time. The data is summarized in Table 4.

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Table 4

	Example-1	Example-2	Comparative Example A
Squeezability (of the co-extruded sample (from a tube after 7 days storage)	Good	Good	Sample very hard. Not squeezable
Cleaning and polishing characteristics	Good	Good	-
Transmittance value of the gel phase (day 1)	13.5	13.5	18
Transmittance value of the gel phase (after 3 months storage)	11.0	10.5	0.1

As would be apparent from the above, the selective multiphase formulations of the invention involving the gel phase and the opaque phase (Example 1 and 2) having the mobile phase ingredients within the selected concentration range provided for greater flexibility in incorporation of benefit agents especially abrasives in the formulations of the invention which showed good cleansing and polishing effects while maintaining formulation stability.

Importantly, it is found that the other multi-phase formulations without such balanced mobile phase (Comparative Example A) failed to achieve the desired formulation stability.

It is thus possible following the invention to achieve stable multiphase toothpaste of various gel-opaque combinations where each of the phases would be self

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sufficient to render desired cleansing and polishing effect. Importantly, transparent gel phase which can now include abrasive not only facilitate the aesthetic appeal of the multiple toothpaste but also contribute towards achieving
5 desired cleaning and polishing effects. Importantly, the concentration of soluble ingredients in the opaque and gel formulations when effectively matched within the selected range further prevent ingredient migration and destabilization of the formulation during shelf-life apart
10 from improving cleansing and polishing effect. The multiple toothpaste of the invention is thus directed to serve not only to add to the aesthetic value of such multiphase toothpaste but also achieve the intended cleaning and polishing effects without sacrificing the much desired
15 formulation stability of such multiphase toothpastes.

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CLAIMS:

1. A multiphase toothpaste comprising an opaque phase and a transparent gel phase, each said phase having a mobile
5 phase with an effective amount of cleansing or polishing agents suspended therein, and wherein of the ingredients making up more than 2% of each mobile phase a corresponding amount of said ingredients is present in the other mobile phase such that no substantial transfer of
10 ingredients occurs between the mobile phases.
2. A multiphase toothpaste as claimed in claim 1 wherein the mobile phase ingredients comprising more than 2% of said mobile phase of each of said opaque/gel phases of the
15 multiphase combination do not differ by more than 35% across the different opaque/gel phases.
3. A multiphase toothpaste as claimed in claim 1 or 2 wherein the mobile phases represent from 20 to 95% by weight of
20 their respective phases.
4. A multiphase toothpaste as claimed in claim 1 or 2 wherein the mobile phases represent from 30 to 90% by weight of their respective phases.
25
5. A multiphase toothpaste as claimed in any of claims 1 to 4 wherein the opaque phase comprises abrasives in the range of 4 to 70% by weight of the opaque phase and the gel phase comprises abrasives in the range of 4 to 40% by
30 weight of the gel phase.

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6. A multiphase toothpaste as claimed in any of claims 1 to 5 wherein the opaque phase and the gel phase additionally comprise humectants in the range of 1 to 90% and binders in the range of 0.1 to 25% by weight of the respective phases.

7. A multiphase toothpaste comprising two side by side transparent-gel and opaque phases, said transparent-gel phase present in an amount in the range of 40 to 60 volume % and said opaque phase present in an amount in the range of 40 to 60 volume % by volume of the toothpaste and wherein each said phase have effective amount of cleansing/polishing agents and comprising of a mobile phase and selected such that the major mobile phase ingredients of said mobile phase of each of said opaque/gel phases of the multiphase combination do not differ by more than 50% across the opaque/gel phases

8. A multiphase toothpaste as claimed in claim 7 wherein the said transparent-gel phase is present in an amount in the range of 44 to 50 volume % and said opaque phase is present in an amount in the range of 50 to 56 volume % by volume of the toothpaste.

9. A multiphase toothpaste according to any preceding claim comprising a plurality of transparent gel phases structured as stripes within a single opaque phase.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61Q A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	US 4 456 585 A (HAYES HARRY ET AL) 26 June 1984 (1984-06-26) claim 1 column 1, lines 38-43 column 1, line 58 - column 2, line 9 column 2, lines 31-43 column 8; example 3	1-9
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members

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