

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
14 September 2006 (14.09.2006)

PCT

(10) International Publication Number  
**WO 2006/096893 A2**

(51) International Patent Classification:  
A61K 6/00 (2006.01)

(21) International Application Number:  
PCT/ZA2006/000036

(22) International Filing Date: 9 March 2006 (09.03.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
2005/2024 10 March 2005 (10.03.2005) ZA

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DENTAL BARRIER COMPOSITION

(57) Abstract: The invention provides a dental barrier composition for use in dental procedures, said composition including one or more microbicidal and/or microbistatic substance or composition, one or more carrier fluid having a viscosity between 15 mPa.s and 10 000 mPa.s, said carrier including one or more thickening, gelling, and or suspending agents selected from the group including, but not limited to, hydroxy propyl methyl cellulose, hydroxy ethyl cellulose, methyl cellulose, chitosan, glycerol, silica or fumed silica, guar gum, povidon, pectin, gelatine, and ceratonia, provided that where hydroxy ethyl cellulose is used it is used in combination with at least one other carrier. The invention further provides for use of the composition and a method of medicating a root canal.



WO 2006/096893 A2

## Dental Barrier Composition

### Field of the Invention

5 The invention relates to a barrier composition for disinfecting and maintaining sterile a root canal and/or suspending and aiding in removal of particles and lubrication during instrumentation in dental procedures.

### Background to the Invention

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The inventor is aware that in the preparation of root canal procedures the issue of infection often arises. Sometimes the infection only manifests later and is attributed to a leaky filling or restoration, however, the inventor believes that the infection starts at the time the root canal procedure is being performed as it is very difficult to ensure that the  
15 open root canal remains sterile throughout the procedure as well as preventing the entrapment of debris consisting of lipids, antigens, lipopolysaccharides, proteins bacteria etc in an infectious layer.

The inventor believes that the problem lies in one or more of the following areas,  
20 although there may be other factors present as well. Firstly, the Gutta Percha points used for sealing may be unsterile as may any other devices used in the process of preparing a root canal, secondly, the tongue or saliva of the patient will often reach out to the tooth being worked on, usually involuntarily, and re-infect a just sterilized area unbeknownst to

the dentist. Thirdly, re-infection may occur from contaminated endodontic files. Yet further, the sterilizing compositions currently in use have a water like low viscosity and drain from the area to which they are applied.

## 5 Summary of the Invention

The invention provides a dental barrier composition for use in dental procedures, said composition including:

- one or more microbicidal and/or microbistatic substance or composition;
- 10 - one or more carrier fluid having a viscosity of between 15 mPa.s and 10 000 mPa.s, said carrier including one or more thickening, gelling, and or suspending agents selected from the group including, but not limited to,
  - hydroxy propyl methyl cellulose;
  - hydroxyl propyl cellulose;
  - 15 - hydroxy ethyl cellulose;
  - methyl cellulose;
  - chitosan;
  - glycerol;
  - silica or fumed silica;
  - 20 - guar gum;
  - Povidone;
  - pectin;
  - gelatine; and

- carob bean gum;

provided that where hydroxy ethyl cellulose is used it is used in combination with at least one other carrier.

5 It is believed that hydroxyl propyl methyl cellulose is believed to be better than hydroxyl ethyl cellulose as it is believed that the propyl groups bind fatty substances which leads to better cleaning of the root canal as well as improving spreadability thereof.

The composition may include one or more flavourant, colourant, and diluent.

10

The dental barrier composition may be a temporary dental barrier composition.

The microbicidal or microbistatic substance may be chlorhexadine or a salt or derivative thereof.

15

The chlorhexadine may be from 0.01% to 5% by mass of the composition.

The chlorhexadine may be chlorhexadine digluconate, however other salts or bases could be used.

20

The carrier may be a gel.

The gel may include from 0.05% to 50% by mass of one or more thickening, gelling, and or suspending agents.

The composition may include non-ionic surfactants.

5

The microbicidal or microbistatic substance may include one or more disinfectants selected from the group including:

- an amine oxide;
- a hypochlorite;
- 10 - an amphoteric surfactant such as a betaine, for example, cocamidopropyl betaine;
- an anionic surfactant such as sodium laural ether sulphate or sodium laurel sulphate;
- triclosan;
- benzalkonium chloride;
- 15 - bronopol;
- chlorxylonol;
- tricresol formaldehyde (tcf); and
- chloro phenol – camphor - menthol (cpmcp).

20 Combinations of microbistatic or microbicidal compounds may be used, for example, triclosan and chlorhexadine, chlorxylonol and chlorhexadine, and/or benzalkonium chloride and chlorhexadine.

Yet other ingredients of the composition include one or more:

- benzocaine;
- calcium hydroxide;
- calcium phosphate;
- 5 - steroids;
- anti-inflammatories; and
- antibiotics.

The composition may also include flavourants and sweeteners such as aspartame,  
10 sorbitol, and the like.

The composition may be water soluble and thus the constituents may be water soluble or water solubalized substances for easy wash out and handling characteristics.

15 The composition may include one or more of a local anesthetic, an anti-inflammatory, a pain reliever, or other medically active substance it may be used as an interim root canal medicament, however, the basic composition may be used as a medicament and does not have to contain any of the last mentioned substances.

20 The invention extends to the use of the above composition for disinfecting a root canal during instrumentation and maintaining the sterility thereof until the root canal has been closed up. The invention can be used on both 'milk ' teeth and permanent teeth.

The use of the composition may include applying the composition all over the pulpal chamber and surrounding periodontum as well as the root canal.

5 The use of the composition may include applying the composition to periodontum thereby to lower the bacterial count of the periodontum, for example, the periodontal pocket.

The use of the composition may include applying the composition to a region of the oral cavity either before or after, or both before and after oral surgery.

10

The use thereof may keep the root canal aseptic while performing other tasks like testing the length (working length) with, for example, a Gutta-Percha (GP) point or any purposefully designed instrument, as well as during the taking of x-ray's

15 The use prevents excessive saliva contamination and bacteria by serving as a temporary barrier.

The composition could also be used as a carrier substance for other medicaments, for example, Calcium Hydroxide powder.

20

The use prevents or lowers the risk of formation of a infectious layer or infection prone layer.

The use of the composition may result in suspending of particles and dissolving of lipid membranes by the non-ionic surfactants resulting in the suspending of the particles and easier wash out as well as removal of lipids leaving a cleaner root canal

- 5 The use of the composition may be advantageous in that it leads to lubrication of endodontic files leading to better instrumentation and less fracturing of the instruments.

Another advantage of using the composition is that there is less chance of irritating apical tissue due to the composition being a gel or suspending agent having a high viscosity.

10

Another advantage of the composition is that there is a perceived lower chance of injecting the substance into the periapical area which causes possible irritation and / or necroses and / or inflammation of the surrounding tissue when compared to traditional 1% Sodium Hypo Chloride or peroxide rinses.

15

Yet further, the composition may be used safely with most root canal medicament or sealers.

Other uses for the composition include:

20

As a microbicide for a wide spectrum anti-bacterial, anti-fungal, and/or anti viral uses that can be applied topically, for example, to the vagina, penis, rectum, genitalia or urogenital area, orally or oropharyngeally.

Dental / Oral disinfectant, for example, for Periodontitis / Gingivitis it can be applied as a gel or a mouth rinse, or by a professional

5 As a spermicide.

Treatment of cold sores.

Denture disinfectant and tissue conditioner.

10

The invention further provides a method of medicating a root canal, said method including applying a dental barrier composition as described above to a root canal and leaving said composition inside the root canal when the root canal procedure is completed.

15

The method may include the steps of applying the composition to the root canal and/or the surrounding perodontium, removing the composition, the reapplying the composition for it to remain there as the root canal procedure is completed.

20

If the sensitivity reaction in a normal tooth is due to water movement within the tooth tubuli, then it is possible to treat a root canal system with water as the carrier medium, to allow a small enough molecule to diffuse into the tubuli, along the path of water and bring

about a greater degree of healing and less symptoms associated with root canal treatment. This may be referred to as the wet healing theory.

5 Currently a dry canal is advocated, however, in order to be sure of the removal of toxic substances like sodium hypochloride. rinsing with sterile water might be advocated, but in the end the canal get dried and a medicament is placed therein.

Sometimes these are desirable chemicals like calcium hydroxide or calcium phosphate or zinc oxide.

10

The inventor postulates a greater ability of a root canal system to heal if sterile water is introduced into the root canal at the time of medicating.

15 The substances used in such a wet treatment may be water soluble if diffusion is needed or not water soluble if precipitation is required.

It may further be possible to treat the surrounding tissue e.g. the bone and periodontal ligament area by diffusion of desired molecules.

20 Thus, if it is possible to use water to further / aid in the treatment of a root canal then it will be possible to use organic solvent or fat as solvent for diffusion of other substances.

It is postulated from clinical observations that if sterile water is introduced at the time of medicating and calciumhydroxide or /and zincoxide or/and beta tricalcium phosphate powder is mixed into the gel which then serves as a carrier, and the mixture is then introduced into a wet root canal and then sealed off for the interim, bone healing may be promoted and associated pain reduced . Currently, the use of CaOH<sub>2</sub> is advocated with local anaesthetic or water and these are mixed to a paste and applied to the canal, however, the volume of water is not the same as filling the root canal with a liquid.

### Examples of the Composition and Uses Thereof

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The examples that follow are merely a selection of possible compositions which illustrate the invention and are not intended to limit the invention in any way whatsoever.

#### Composition 1

15

1. Chlorexidine (2 mass%)
2. Hydroxy Ethyl Cellulose or Hydroxy Propyl Methyl Cellulose (0,2 – 5 mass%)
3. Colour Red
4. Aqua (deionised water)
- 20 5. calcium bicarbonate (1- 2 mass%)

#### Composition 2

1. Chlorhexidine (1 mass%)
2. Hydroxy Ethyl Cellulose (0,2 – 5 mass%)
3. Povidon (5 mass%)
4. Aqua
- 5 5. Colour Red

### Composition 3

1. Chlorhexidine (0,5 mass%)
- 10 2. Chitosan gel (5% - 60 mass%)
3. Calcium Hydroxide (1 – 30 mass%)
4. Hydroxy Ethyl Cellulose or Hydroxy Propyl Methyl Cellulose (0,2 – 5 mass%)
5. Aqua
6. Colour Red
- 15

### Composition 4

1. Chlorhexidine (0,2 – 5 mass %)
2. Hydroxy Ethyl Cellulose or Hydroxy Propyl Methyl Cellulose (0,2 – 5 mass%)
- 20 3. Aqua
4. Colour Red
5. Cocamidopropyl betane (0,1 – 10 mass%)
6. Laural amine oxide (0,1 – 10 mass%)

**Composition 5**

1. Chlorhexidine (0,2 – 5 mass%)
- 5 2. Hydroxy Propyl Methyl Cellulose (0,2 – 5 mass%)
3. EDTA (0,005 – 1 mass%)
4. Aqua
5. Colour Red

10 **Composition 6**

1. Chlorhexidine (1 mass%)
2. Hydroxy Ethyl Cellulose ( 2.5 mass%)
3. Hydroxy Propyl Methyl Cellulose (2.5 mass%)
- 15 4. Aqua
5. Colour Red
6. Glycerol 1 vol%

This had a viscosity of 7500 mPa.s on a Brookfield LVT 1 Viscometer spindle RV6 at a  
20 speed of 50.

**Composition 7**

1. Chlorhexadine 2 mass%
2. Hydroxy Propyl Methyl Cellulose 2.5 mass%
3. Aqua
4. Colour

5

**Composition 8**

1. Hydroxy Propyl Methyl Cellulose ) 1 - 2 mass%
2. Chlorhexidine 2 vol%
- 10 3. Glycerol 1 vol%
4. Aqua
5. Colour
6. Triclosan 0.2% m/v

15 This composition had a viscosity of 2920 mPa.s when measured on a Brookfield LVT 1 viscometer with spindle RV6 at a speed of 50.

**Composition 9**

- 20 1. Hydroxy Propyl Methyl Cellulose 3 mass%
2. Chlorhexidine 2 mass%
3. Aqua
4. Glycerol 1 vol%

5. Colour
6. triclosan 0.2 m/v%

This composition had a viscosity of 4055 mPa.s measured on a Brookfield LVT 1  
5 viscometer on a spindle RV3 at a speed of 20.

### Composition 10

1. Hydroxy Propyl Methyl Cellulose 3 mass%
- 10 2. Chlorhexidine 2 mass%
3. Aqua
4. Alcohol 2 – 4 mass%
5. Colour
6. With or without preservative to prevent contamination

15

### Composition 11

1. Hydroxy Propyl Methyl Cellulose 3 mass%
2. Chlorhexadine gluconate 2 vol%
- 20 3. Aqua
4. Glycerol 0.5 to 5 vol%
5. Triclosan 0.2 m/v%

**Composition 12**

1. Hydroxy Propyl Methyl Cellulose 1 mass%
- 2 Aqua
- 5 3. Chlohexidine 2 vol%

This composition has a viscosity of 44 mPa.s when measured on a Brookfield LVT 1 viscometer with a spindle RV 3 at a speed of 50.

- 10 Examples of how the composition, for example as per Compositions 1 to 10 above, is used include, but are not limited to, the following:

The gel is applied with e.g. a needle and a syringe (gauge according to the thickness of the gel) inside the root canal or in the pulp chamber.

15

Endodontic hand files / reamers or rotary endodontic file powered by a turbine motor are then inserted into the root canal ( into this gel) for the preparation of the root canal.

- 20 As the gel is worked down into the canal during normal preparation of the root canal it picks up surrounding debri and suspends in the gel. This will then be “washed out”.

When rotary files are used they turn in such away that the gel and debri will be displaced upwards / outwards, therefore, the gel suspends the debri and lowers the chance of it

being worked onto the side and becoming part of the infectious layer while the rotation motion of the reamers are upwards and outwards.

Before the next file or any other instrument, is inserted into the canal, more gel could be  
5 applied.

When the preparation of the root canal is finished then the gel is washed out, for example with water, or removed via endodontic suction unit, in order to check if the canal is clean /dry (i.e no sign of blood, puss or any undesirable materials). If the dentist thinks the gel  
10 is 'dirty' it gets washed out and new gel gets applied until the dentist thinks the canals are clean and debri free – then only is preparation finished.

The gel can be applied again when a test measurement is taken with example using a Gutta Percha (GP) point. GP points are usually not sterile / aseptic.  
15

The gel is compatible with most dental disinfectants and will not create toxic substances or precipitate, therefore products like CPMCP and TCF could be used in conjunction with this product.

20 It would be possible to use calcium hydroxide as the secondary disinfectant or to enhance mineralization of the periapicale area while preparing and disinfecting a root canal.

Use of a gel prepared in accordance with compositions 1 to 10 has resulted in a clinically observed reduction in pain and infection in root canal treatment.

### Examples of the Wet Treatment for Root canals

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If a gel as described in Compositions 1 to 11 above is used in conjunction with water the chlorhexidine portion, which is water soluble, will then diffuse along the path of water, further down the root canal, than where the gel was applied (there has to be a physical connection between the water and the gel however).

10

The penetration ability of calcium hydroxide into the tubuli can be greatly enhanced if water is introduced into the root canal prior to applying the medicament -- it is however likely that because of the concentrations that are used it will precipitate and stay in equilibrium of diffusion.

15

The above also applies to  $\text{Ca}(\text{PO}_4)$ ;  $\text{NaH}_2(\text{PO}_4)$ ; and  $\text{Ca}(\text{OH})_2$ , zinc oxide, and chitosan whether used alone or in combinations

It is therefore further possible to disinfect the periodontal ligament area with a desired  
20 disinfectant -- this would then apply to treatment of e.g. a perio-endo lesion or an endo-perio lesion.

It is an advantage of the invention, at least as illustrated, that unlike usual root canal disinfection which last 2 to 3 minutes, use of the compositions of the invention results in prolonged disinfection as the composition remains in contact with the disinfected area.

**Claims**

1. A dental barrier composition for use in dental procedures, said composition including:

- 5 - one or more microbicial and/or microbistatic substance or composition;
- one or more carrier fluid having a viscosity of between 15 mPa.s and 10 000 mPa.s, said carrier including one or more thickening, gelling, and or suspending agents selected from the group including, but not limited to,

- 10 - Hydroxy Propyl Methyl Cellulose;
- Hydroxyl Propyl Cellulose;
- Hydroxy Ethyl Cellulose;
- Methyl Cellulose;
- Chitosan;
- Glycerol;
- 15 - Silica or fumed silica;
- Povidone;
- Pectin;
- Gelatine; and
- Guar bean gum;

20 provided that where Hydroxy Ethyl Cellulose is used it is used in combination with at least one other carrier.

2. A composition as claimed in claim 1, including one or more flavourant, colourant, and diluent.

3. A composition as claimed in claim 1 or claim 2, which is a temporary dental  
5 barrier composition.

4. A composition as claimed in any one of the preceding claims, wherein the one or more microbicidal and/or microbistatic substance is chlorhexadine or a salt or derivative thereof.

10

5. A composition as claimed in claim 4, wherein the chlorhexadine is from 0.01% to 5% by mass of the composition.

6. A composition as claimed in claim 4 or claim 5, wherein the chlorhexadine is in  
15 the form of chlorhexadine digluconate.

7. A composition as claimed in any one of the preceding claims, wherein the carrier is a gel

20 8. A composition as claimed in claim 7, wherein the gel includes from 0.05% to 50% by mass of one or more thickening, gelling, and or suspending agents.

9. A composition as claimed in any one of the preceding claims, which includes non-ionic surfactants.

10. A composition as claimed in claim 1, wherein the one or more microbicidal and/or microbistatic substance includes one or more disinfectants selected from the group including:

- an amine oxide;
- a hypochlorite;
- an amphoteric surfactant;
- 10 - an anionic surfactant;
- triclosan;
- benzalkonium chloride;
- bronopol;
- chlorxylonol;
- 15 - tricresol formaldehyde; and
- chloro phenol – camphor - menthol.

11. A composition as claimed in any one of the preceding claims, which includes one or more of:

- 20 - benzocaine;
- calcium hydroxide;
- calcium phosphate;
- steroids;

- anti-inflammatories; and
- antibiotics.

12. A composition as claimed in any one of the preceding claims which is water  
5 soluble.

13. Use of a composition as claimed in any one of the preceding claims for  
disinfecting a root canal during instrumentation and maintaining the sterility thereof until  
the root canal has been closed up.

10

14. Use as claimed in claim 13, which includes applying the composition to the pulpal  
chamber, the surrounding periodontum, and the root canal.

15. Use as claimed in claim 13 or claim 14, including applying the composition to  
15 periodontum thereby to lower the bacterial count of the periodontum.

16. Use as claimed in any one of claims 13 to 15, including applying the composition  
to a region of the oral cavity either before or after, or both before and after oral surgery.

20 17. Use as claimed in any one of claims 13 to 16, wherein the composition maintains  
the root canal aseptic while performing other tasks like testing the length of a working  
instrument and/or during the taking of x-ray's

18. Use as claimed in any one of claims 13 to 17 to prevent excessive saliva contamination by serving as a temporary barrier.
19. Use as claimed in any one of the preceding claims wherein the composition is also  
5 used as a carrier substance for one or more medicaments.
20. Use as claimed in any one of claims 13 to 19, which use results in suspending of particles and dissolving of lipid membranes by non-ionic surfactants resulting in the suspending of the particles and easier wash out as well as removal of lipids leaving a  
10 cleaner root canal.
21. Use as claimed in any of claims 13 to 19, which use lubricates endodontic files leading to better instrumentation and less fracturing of the instruments.
- 15 22. Use as claimed in any one of claims 13 to 21, wherein the composition is applied to the gingival to treat gingivitis and periodontitis.
23. A method of medicating a root canal, said method including applying a dental barrier composition as claimed in any one of claims 1 to 12 to a root canal and leaving  
20 said composition inside the root canal when the root canal procedure is completed.
24. A method as claimed in claim 23, which method includes the steps of applying the composition to the root canal and/or the surrounding perodontium, removing the

composition, the reapplying the composition for it to remain there as the root canal procedure is completed.