



AU9514838

(12) PATENT ABRIDGMENT (11) Document No. AU-B-14838/95
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 699521

(54) Title
DENTAL FILLING COMPOSITION AND METHOD

International Patent Classification(s)
(51)⁶ **A61K 006/087**

(21) Application No. : **14838/95**

(22) Application Date : **14.03.95**

(30) Priority Data

(31) Number	(32) Date	(33) Country
217998	25.03.94	US UNITED STATES OF AMERICA

(43) Publication Date : **05.10.95**

(44) Publication Date of Accepted Application : **03.12.98**

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(56) Prior Art Documents
WO 93/0176
CA 121990
US 5236362

(57) Claim

3. A root canal sealing dental filling composition, comprising; filler and liquid polymerizable organic monomers polymerizable in a tooth root canal to form a thermoplastic linear polymer, said polymerizable organic monomers comprising polymerizable diepoxide monomer and amine monomer, said amine monomer being a primary monamine and/or a dissecondary diamine, said filler comprising 40 to 85 percent by weight of said composition and providing said composition with a radiopacity of at least 3 mm/mm aluminum, said composition being formed from two-components which are adapted to be mixed together to initiate polymerization.

AUSTRALIA
PATENTS ACT 1990
COMPLETE SPECIFICATION

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INVENTION TITLE:

Dental filling composition and method

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

The invention relates to dental filling composition. A dental filling composition in accordance with the invention is adapted to form epoxide-amine addition polymers with fillers. The dental filling composition include filler and diepoxides, primary monoamines and/or dissecondary diamines. Dental filling compositions in accordance with the invention polymerize to form a thermoplastic linear polymer which is adapted to seal a canal in a tooth root. The filler is present in an amount of from 40 to 85 percent by weight of the dental filling composition. The dental filling material is formed by polymerization and has radiopacity of greater than 3 mm/mm Al. The clinical working time is up to about 2 hours and the setting time is from about 0.5 to about 40 hours.

Blahman et al in USSR 311637 and 311638 disclose dental filling materials. Feichtinger et al in U.S. Patent 3,317,469 discloses reaction product of a glycidyl polyether and diaminomethyltricyclodecane.

Lee in U.S. Patent 3,327,016 discloses epoxide compositions cured with 1,4-bis(aminomethyl)cyclohexane. Toepel et al in U.S. Patent 3,673,558 discloses polyaddition products and process for their manufacture. Rogier in U.S. Patent 4,229,376 discloses polycyclic polyamines. Rogier in U.S. Patent 4,296,004 discloses polycyclic polyamines. Hörhold et al in U.S. Patent 4,308,085 discloses process for the preparation of high molecular thermoplastic epoxide-amine-polyadducts. Fujisawa et al in U.S. Patent 4,931,096 discloses sealer for filling a dental root canal. Chang et al in U.S. Patent 4,950,697 discloses thermoplastic and injectable endodontic filling compositions. In U.S. Patent 5,236,362 a root canal filling and adhesive composition is described. Polyfunctional aliphatic and aromatic amines such as hexamethylenediamine, di-ethylene triamine, triethylene tetramine, methylene dianiline or m-phenylenediamine used for the epoxide-amine polymerisation as well as tertiary amine initiators such as 2,4,6-tris(dimethylaminoethyl)phenol or triethanol amine lead to insoluble cross linked network polymers. Cross linked polymers generally tends to higher shrinkage during polymerization which gives rise to the formation of edge cracks and gaps.

Prior art dental filling materials for tooth root canals have relatively long setting time, high viscosity and discolor. Paraformaldehyde is sometimes used, as see Soviet Union Patent 1510131, and Chemical Abstracts 115 (1991) 78952z. Other products contain low molecular weight organic substances like CHI₃, as see Japanese Patent 9127308 A2, and Chemical Abstract 115 (1991) 78973g. Aliphatic and cycloaliphatic epoxides have been applied in dental filling materials hardened with imidazoline or BF₃, as see Soviet Union Patents 549150, 545353, 52106 and 349396, but are known to have mutagenic properties. Other dental filling materials contain epoxides, diethylenediamine and fillers like porcelain powder, quartz and zeolite, as see Soviet Union Patents 311638 and 311637. These fillers do not provide substantial radiopacity. The use of a setting aliphatic amine alone is disadvantageous because it does not withstand tensions caused by shrinkage and change of temperature. Aliphatic amines cause side reactions (etherification of hydroxyl groups) in epoxide-amine addition polymerization. Consequently a portion of amine groups are unreacted.

High molecular weight linear epoxide-amine addition polymers (M_n 10000 to 20000 g/mol) have been

synthesised using diglycidyl ethers of bisphenols and N,N'-dibenzylamines, as see DD 141667, US 4308085, GB 2045269, CS 27363; or primary monamines as see DD 154945, DD 214381, DD 261365. The addition polymers were prepared as adhesives for optical and electrophotographic application.

Advantageously, the invention provides a dental filling material which provides a radiopacity of at least 3 mm/mm Al.

10 The invention also advantageously provides a tooth root filling composition which has a radiopacity of at least 3 mm/mm Al and a viscosity less than 20,000 cp.

BRIEF DESCRIPTION OF THE INVENTION

15 According to one aspect of the invention there is provided a root canal sealing dental filling composition, comprising: a filler and liquid polymerizable organic monomers polymerizable in a tooth root canal to form a thermoplastic linear polymer which is readily soluble in an organic solvent, said filler
20 comprising 40 to 85 percent by weight of said composition and providing said composition with a radiopacity of at least 3 mm/mm aluminum, wherein, in use, said monomers polymerize to seal said tooth root canal, and wherein said polymerizable monomers are diepoxides selected from diglycidyl ether of
25 bisphenol-A, diglycidyl ether of bisphenol-F, butanediol diglycidyl ether of Δ^3 -tetrahydrophthalic acid diglycidyl ester, and disecundary diamines.

According to another aspect of the invention there is
30 provided a root canal sealing dental filling composition,

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comprising: filler and liquid polymerizable organic monomers polymerizable in a tooth root canal to form a thermoplastic linear polymer, said polymerizable organic monomers comprising polymerizable diepoxide monomer and amine monomer, said amine monomer being a primary monamine and/or a dissecondary diamine, said filler comprising 40 to 85 percent by weight of said composition and providing said composition with a radiopacity of at least 3 mm/mm aluminum, said filler being La_2O_3 , ZrO_2 , BiPO_4 , BaWO_4 , SrF_2 , Bi_2O_3 and/or polymer granules.

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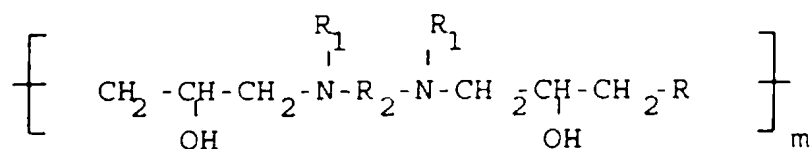
According to a further aspect of the invention there is provided a root canal sealing dental filling composition, comprising; filler and liquid polymerizable organic monomers polymerizable in a tooth root canal to form a thermoplastic linear polymer, said polymerizable organic monomers comprising polymerizable diepoxide monomer and amine monomer, said amine monomer being a primary monamine and/or a dissecondary diamine, said filler comprising 40 to 85 percent by weight of said composition and providing said composition with a radiopacity of at least 3 mm/mm aluminum, said composition being formed from two-components which are adapted to be mixed together to initiate polymerization.

According to yet another aspect of the invention there is provided a root canal sealing dental filling compositions, comprising: filler and liquid polymerizable organic monomers polymerizable in a tooth root canal to form a thermoplastic linear polymer; said polymerizable organic monomers comprising polymerizable diepoxide monomer and amine monomer said amine monomer being a primary monoamine and/or a dissecondary diamine, said filler comprising 40 to 85 percent by

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weight of said composition and providing said composition with a radiopacity of at least 3 mm/mm aluminum, said monomers being polymerizable to form said thermoplastic linear polymer being within the scope of general formula:

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10 wherein R is a moiety formed from a diepoxide;

R₁ is a substituted alkyl, having from 2 to 12 carbon atoms, cycloalkyl, substituted cycloalkyl, aryl having from 6 to 20 carbon atoms, substituted aryl, arylalkyl, or substituted arylalkyl.

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R₂ is a difunctional alkyl, substituted alkyl having from 2 to 12 carbon atoms, cycloalkyl, substituted cycloalkyl, aryl having from 6 to 20 carbon atoms, substituted aryl, arylalkyl, or substituted arylalkyl,

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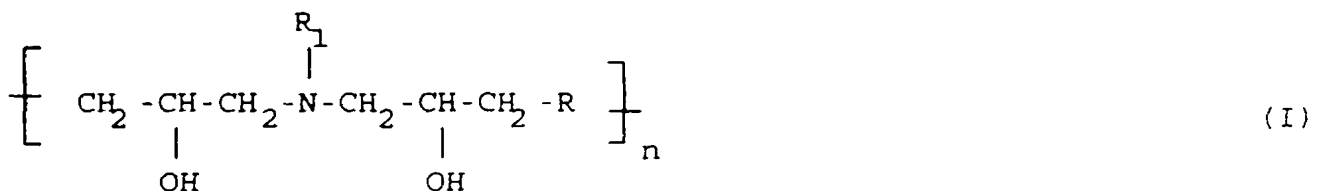
and m, each independently is an integer from 1 to 1000, and when substituted R₁ and R₂ are independently substituted with one or more alkoxy, halogen, nitrate, acyl or carboxy alkyl moieties.

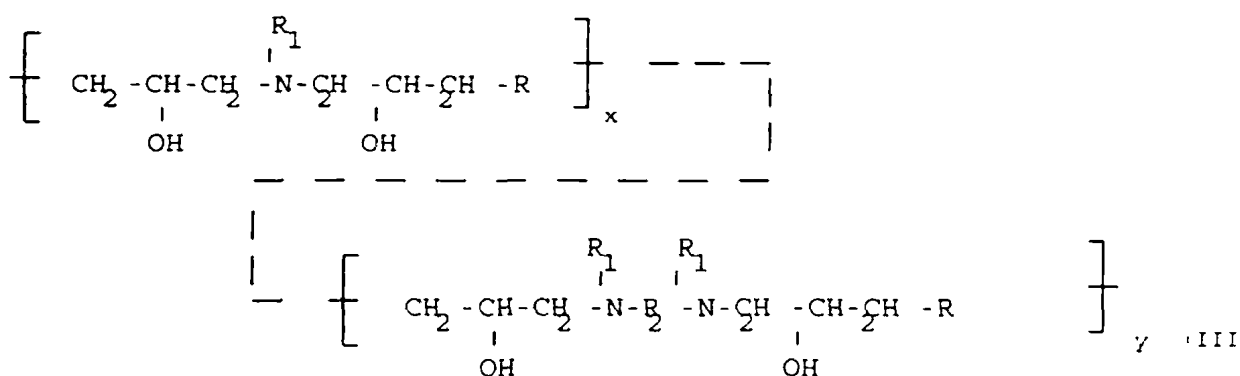
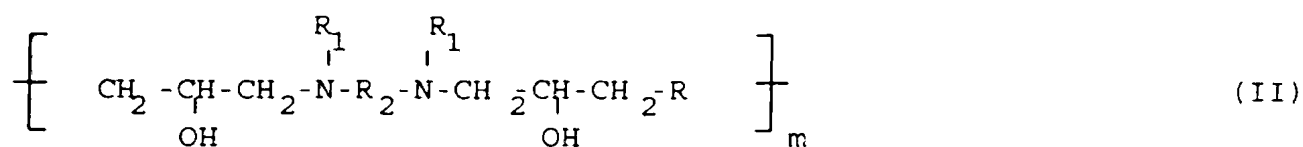
25 According to still a further aspect of the invention there is provided a root canal sealing dental filling composition, comprising filler and liquid polymerizable organic monomers polymerizable in a tooth root canal to form a thermoplastic linear polymer, said polymerizable organic monomers comprising
30 polymerizable diepoxide monomer and amine monomer said amine monomer being a primary monoamine and/or a dissecondary diamine,

DETAILED DESCRIPTION OF THE INVENTION

Dental filling material in accordance with the invention includes liquid polymerizable organic monomers and fillers, and is adapted for sealing tooth root canal such as are formed by root canal procedures. The polymerizable organic monomers are diepoxides, primary monoamines and/or disecundary diamines. Unsubstituted aliphatic primary monoamines, which form with diepoxide, crosslinked polymer, are not preferred as polymerizable organic monomers in dental filling material in accordance with the invention. Filler content in dental filling material in accordance with the invention is preferably from 40 to 85 percent by weight of the dental filling material as inorganic and/or organic filler particles.

The dental filling material may polymerize to form epoxide-amine addition polymers within one or more of the general formulas I, II and III as follows:





wherein R is a moiety formed from a diepoxide;

R₁ is a substituted alkyl, having from 2 to 12 carbon atoms, cycloalkyl, substituted cycloalkyl, aryl having from 6 to 20 carbon atoms, substituted aryl, arylalkyl, or substituted arylalkyl,

R₂ is a difunctional alkyl, substituted alkyl having from 2 to 12 carbon atoms, cycloalkyl, substituted cycloalkyl, aryl having from 6 to 20 carbon atoms, arylalkyl, substituted aryl, substituted arylalkyl,

and n, m, x and y each independently is an integer from 1 to 1,000. When substituted, R₁ and R₂ are independently substituted with one or more alkoxy, halogen, nitrate, acyl or carboxy alkyl moieties.

Diepoxides useful in dental filling compositions in accordance with certain embodiments of the invention include diglycidyl ether of bisphenol-A 2,2-Bis[4-(2,3-epoxypropoxy)phenyl]propane, diglycidyl ether of bisphenol-F 5 (is an isomeric mixture of Bis[4-(2,3-epoxypropoxy)phenyl]methane and the 2,4-homologous CIBA-Geigy), butanediol diglycidyl ether, N,N-diglycidylaniline, and Δ^3 -tetrahydrophthalic acid (sometimes referred to as bis(2,3-epoxypropoxy) cyclohex-3-ene dicarboxylic ester). Monoamines 10 useful in accordance with certain embodiments of the invention are aniline, p-flouraniline, benzylamine, 1-aminoadamantan, α -phenethylamine, dimethyl (aminomethyl) phosphine oxide and ethanolamine. Diamines useful in accordance with the invention are N,N'-dibenzylethylenediamine, N,N'-dibenzyl-3,6-15 dioxaoctandiamine-1,8,N,N'-dibenzyl-5-oxanonandiamine-1,9,N,N'-dibenzyl-(2,2,4)/(2,4,4) trimethylhexamethylendiamine.

Fillers which may be used in accordance with the invention are, for example, inorganic fillers including 20 inorganic compounds, such as La_2O_3 , ZrO_2 , BiPO_4 , CaWO_4 , BaWO_4 , SrF_2 and Bi_2O_3 ; organic fillers, such as polymer granulate; and combinations of organic and inorganic fillers.

Dental filling material in accordance with the invention 25 advantageously alleviates at least some of the problems of prior art filling material, such as, discoloration and release of formaldehyde. Dental filling material in accordance with the invention advantageously provides the advantages of a low viscosity, relatively short setting time, relatively high 30 solubility in organic solvents, thermoplastic behaviour, and

high radiopacity (RO) i.e., greater than 3 mm/mm Al. Higher values of the radiopacity, for example radiopacity of 5 mm/mm Al, 6 mm/mm Al or greater than 7 mm/mm Al may be obtained using as fillers La_2O_3 , $BiPO_4$, $CaWO_4$ and $BaWO_4$.

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For example a dental filling composition containing diglycidyl ether of bisphenol -A, N,N'-dibenzylethylenediamine and $CaWO_4$ show a viscosity (Brookfield) (η) of 2100 cP, a setting time of 3 hours and a radio opacity (RO) of 9.2 mm/mm 10 Al.

The invention also provides in certain embodiments dental filling material which is prepared from a two component paste system which is preferably introduced into roots using a lentulo 15 or tubular needle because of the low viscosity. The dental filling material of the invention is advantageously formed with low shrinkage. Preferably, the composition polymerizes with less than 3% by volume shrinkage. This prevents contraction gaps and subsequent edge cracks of high shrinking materials. 20 The dental filling material preferably has low absorption of water and good adhesion to dentin. The composites formed therefrom are advantageously readily removable by heating, drilling or solubilizing in organic solvents and are therefore useful as temporary filling materials.

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The composition of the invention preferably has a viscosity of less than 20,000 centipoise, more preferable less than 5,000 centipoise, and is preferably passed through a 1 mm diameter canal of a needle into a tooth root. The polymerizable epoxide 30 monomer used in the composition of the invention preferably is

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a diglycidyl ether of bisphenol-A, diglycidyl ether of bisphenol-F, butanediol diglycidyl ether or Δ^3 -tetrahydrophthalic acid diglycidyl ester.

5 In a preferred embodiment, the composition sets within from 0.5 to 40 hours at 37°C. Preferably, the composition sets within from 0.5 to 3 hours.

Embodiments of the invention will be described with 10 reference to the following examples which should not be construed as limiting on the invention in any way.

In Examples 1-4 setting times stated are determined in accordance with the method of ISO 6876 (1986-12-01: Dental root 15 canal sealing materials).

Example 1

A dental filling material is obtained by mixing 20 homogeneously 3.404 g (10.00 mmol) diglycidyl ether of bisphenol-A, (also referred to as 2,2 bis[4-(2,3-epoxypropoxy) phenyl] propane), 2.404 g (10.00 mmol) N,N'-dibenzylethylenediamine and 18.000 g CaWO₄. This dental material has a viscosity (Brookfield) (η) of 3200 centipoise a 25 setting time of 24 hours (at 37°C) and a radiopacity of 9.5 mm/mm Al. After the



polymerization the dental filling product obtained is soluble in organic solvents such as CHCl_3 or $\text{CHCl}_3/\text{ethanol}$ -mixtures.

Example 2

Usable thermal setting dental filling composition is prepared as a two component paste system of part A and B.

Part A is obtained by mixing homogeneously 142.570 g (374.36 mmol) diglycidyl ether of bisphenol-A (also referred to as 2,2 bis[4-(2,3-epoxypropoxy) phenyl] propane), having a number average molecular weight (M_n) of about 380 g/mol, 11.680 g (37.44 mmol) diglycidyl ether of bisphenol-F (which is an isomeric mixture of bis[4-(2,3-epoxypropoxy)phenyl]methane and bis[2-(2,3-epoxypropoxy) phenyl] methane sold by CIBA-Geigy), and 241.463 g CaWO_4 , 60.366 g ZrO_2 , 0.637 g Fe_2O_3 and 4.277 g aerosil 200 (sold by Degussa).

The paste B is prepared by mixing homogeneously 22.064 g (205.90 mmol) benzylamine, 70.112 g (205.90 mmol) N,N' -dibenzyl-5-oxanonanediamine-1,9, 392.068 g CaWO_4 , 98.017 g ZrO_2 and 25.663 g Aerosil (sold by Degussa). The volume ratio of A mixed with B is 1:1. The setting time is 7 hours (at 37°C) and the working time 2:23 hours (at 23°C), respectively. The composition is characterised by the following values:

radio-opacity (RO) of 11.6 mm/mm Al, flow 45 mm, film thickness 10 μ m, solubility 0.23% (all according ISO 6876), and shrinkage 1.63 volume percent.

Example 3

Useable thermal setting dental filling composition is prepared as a two component paste system of part A and B.

Part A is obtained by mixing homogeneously 128.313 g (337.67 mmol) diglycidyl ether of bisphenol-A (also referred to as 2,2 bis[4-(2,3-epoxypropoxy) phenyl] propane) having a number average molecular weight (M_n) of about 380 g/mol, 10.535 g (33.77 mmol) diglycidyl ether of bisphenol-F (which is an isomeric mixture of bis[4-(2,3-epoxypropoxy) phenyl] methane, and bis[2-(2,3-epoxypropoxy) phenyl] methane sold by CIBA-Geigy), and 294.551 g CaWO_4 , 73.638 g ZrO_2 0.637 g Fe_2O_3 and 1.426 g Aerosil 200.

The paste B is prepared by mixing homogeneously 28.140 g (185.72 mmol) 1-amino-adamantane, 63.241 g (185.72 mmol) N,N' -dibenzyl-5-oxanonanediamine-1,9,8,554 g Aerosil 200, 365.519 g CaWO_4 , 91.380 g ZrO_2 and 11.364 g OL-31 (is a silicon oil sold by Bayer). The volume ratio of A mixed with B is 1:1. The setting time is 8 hours (at 37°C) and the working time is 16 hours at (23°C), respectively. The composition is

characterised by following values: radio-opacity (RO) of 10.1 mm.mm Al, flow 35 mm, film thickness 15 μ m, solubility 0.27 % (all according ISO 6876), and shrinkage 1.13 volume percent.

Example 4

A usable thermal setting dental filling material is obtained by mixing homogeneously 2.000 g (5.88 mmol) diglycidyl ether of bisphenol-A, 1.413 g (5.88 mmol) N,N'-dibenzylethylenediamine and 8.000 g La_2O_3 . The setting time is 6 hours (at 37°C) and the radio-opacity is 6.3 mm/mm Al.

It should be understood that while the present invention has been described in considerable detail with respect to certain specific embodiments thereof, it should not be considered limited to such embodiments but may be used in other ways without departure from the spirit of the invention and the scope of the appended claims.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or group of integers or steps but not the exclusion of any other integer or group of integers or steps.



The claims defining the invention are as follows:

1. A root canal sealing dental filling composition, comprising: a filler and liquid polymerizable organic monomers
5 polymerizable in a tooth root canal to form a thermoplastic linear polymer which is readily soluble in an organic solvent, said filler comprising 40 to 85 percent by weight of said composition and providing said composition with a radiopacity of at least 3 mm/mm aluminum, wherein, in use, said monomers
10 polymerize to seal said tooth root canal, and wherein said polymerizable monomers are diepoxides selected from diglycidyl ether of bisphenol-A, diglycidyl ether of bisphenol-F, butanediol diglycidyl ether of Δ^3 -tetrahydrophthalic acid diglycidyl ester, and disecundary diamines.

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2. A root canal sealing dental filling composition, comprising: filler and liquid polymerizable organic monomers polymerizable in a tooth root canal to form a thermoplastic linear polymer, said polymerizable organic monomers comprising
20 polymerizable diepoxide monomer and amine monomer, said amine monomer being a primary monamine and/or a disecundary diamine, said filler comprising 40 to 85 percent by weight of said composition and providing said composition with a radiopacity of at least 3 mm/mm aluminum, said filler being La_2O_3 , ZrO_2 , BiPO_4
25 BaWO_4 , SrF_2 , Bi_2O_3 and/or polymer granules.

3. A root canal sealing dental filling composition, comprising; filler and liquid polymerizable organic monomers polymerizable in a tooth root canal to form a thermoplastic linear polymer, said polymerizable organic monomers comprising

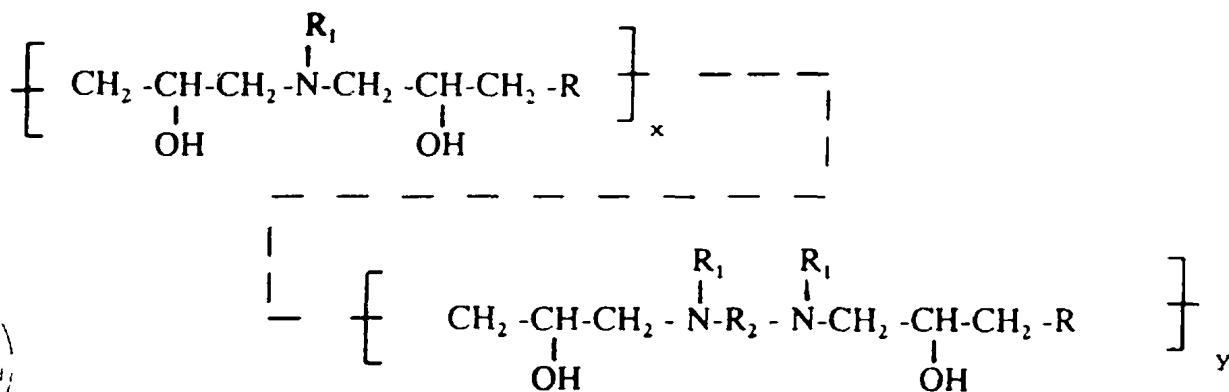


6 to 20 carbon atoms, substituted aryl, arylalkyl, or substituted arylalkyl.

R_2 is a difunctional alkyl, substituted alkyl having from 2 to 12 carbon atoms, cycloalkyl, substituted cycloalkyl, aryl having from 6 to 20 carbon atoms, substituted aryl, arylalkyl, or substituted arylalkyl,

and m , each independently is an integer from 1 to 1000, and when substituted R_1 and R_2 are independently substituted with one or more alkoxy, halogen, nitrate, acyl or carboxy alkyl moieties.

5. A root canal sealing dental filling composition, comprising filler and liquid polymerizable organic monomers polymerizable in a tooth root canal to form a thermoplastic linear polymer, said polymerizable organic monomers comprising polymerizable diepoxide monomer and amine monomer said amine monomer being a primary monoamine and/or a disubstituted diamine, said filler comprising 40 to 85 percent by weight of said composition and providing said composition with a radiopacity of at least 3 mm/mm aluminum, said monomers being polymerizable to form said thermoplastic linear polymer being within the scope of general formula:



- 16 -

wherein R is a moiety formed from a diepoxide;

R₁ is a substituted alkyl, having from 2 to 12 carbon atoms, cycloalkyl, substituted cycloalkyl, aryl having from 6 to 20 carbon atoms, substituted aryl, arylalkyl, or substituted arylalkyl,

R₂ is a difunctional alkyl, substituted alkyl having from 2 to 12 carbon atoms, cycloalkyl, substituted cycloalkyl, aryl having from 6 to 20 carbon atoms, substituted aryl, arylalkyl, or substituted arylalkyl,

and x and y each independently is an integer from 1 to 1,000, and when substituted R₁ and R₂ are independently substituted with one or more alkoxy, halogen, nitrate, acyl or carboxy alkyl moieties.

6. The composition of claim 2, 3, 4 or 5 wherein said monomers are polymerizable to seal said tooth root canal, and said polymerizable organic monomers are diepoxides and diamines, and said thermoplastic linear polymer is readily soluble in organic solvents.

7. The dental filling composition of claim 2, 3, 4 or 5 wherein said amine is benzylamine, adamantanamine or α -phenethylamine; and said diamine is N,N'-dibenzylethylenediamine; N,N'-dibenzyl-3, 6-dioxaoctandiamine-1,8; N,N'-dibenzyl-5-oxanonandiamine-1,9; N,N'-dibenzyl-(2,2,4)-trimethylhexamethylendiamine or N,N'-dibenzyl-(2,4,4)-trimethylhexamethylendiamine.

8. the dental filling composition of claim 1, 2, 3, 4 or 5 wherein said polymer is soluble in CHCl₃, and/or C₂H₅OH.

9. The dental filling composition of claim 1, 2, 3, 4 or 5 wherein said filler provides a radiopacity of at least 6 mm/mm aluminum.

5 10. The dental filling composition of claim 1, 2, 3, 4 or 5 wherein said filler provides a radiopacity of at least 5 mm/mm Al.

11. The dental filling composition of claim 1, 2, 3, 4 or 5 10 wherein said composition sets within from 0.5 to 40 hours at 37°C.

12. The dental filling composition of claim 1, 2, 3, 4 or 5 wherein said composition sets within from 0.5 to 3 hours.

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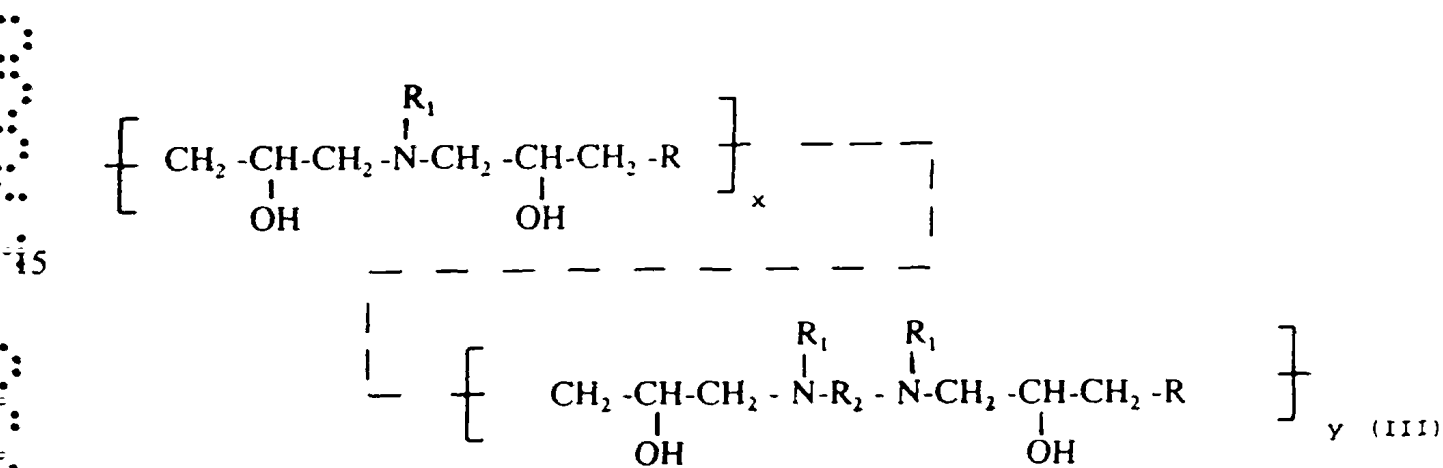
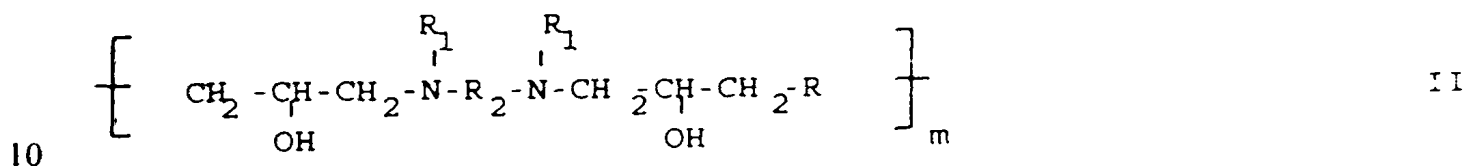
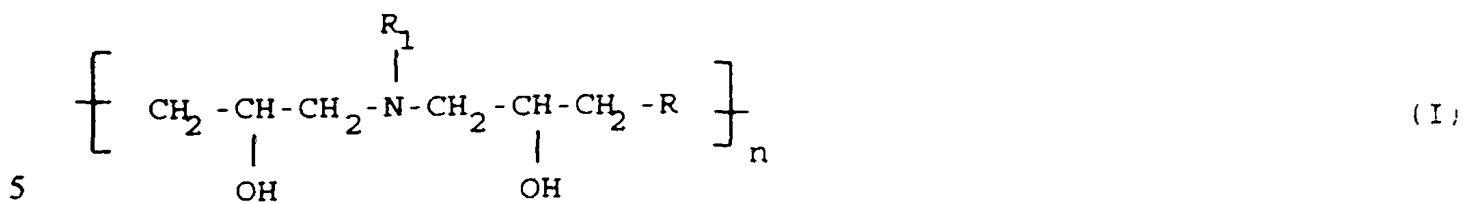
13. The dental filling composition of claim 1, 2, 3, 4 or 5 wherein said composition has a viscosity of less than 5000 centipoise.

20 14. The dental filling composition of claim 1, 2 or 3, wherein said polymer is within the scope of at least one of general formulas:

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wherein R is a moiety formed from a diepoxide;

25 R₁ is a substituted alkyl, having from 2 to 12 carbon atoms, cycloalkyl, substituted cycloalkyl, aryl having from 6 to 20 carbon atoms, substituted aryl, arylalkyl, or substituted arylalkyl,

R₂ is a difunctional alkyl, substituted alkyl having from 2 to 12 carbon atoms, cycloalkyl, substituted cycloalkyl

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16. A dental filling composition and/or a method of sealing a tooth canal substantially as hereinbefore described with reference to the Examples.

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DATED the THIRTIETH day of SEPTEMBER, 1998

10 Dentsply GmbH

by DAVIES COLLISON CAVE

Patent Attorneys for the applicant(s)

DENTAL FILLING COMPOSITION AND METHOD

ABSTRACT OF THE INVENTION

A root canal sealing dental filling composition, includes liquid polymerizable organic monomers and filler. The polymerizable organic monomers include an diepoxide monomer and a primary monoamine and/or a disecundary amine monomer. The filler includes 40 to 85 percent by weight of the composition and provides a radiopacity of at least 3 mm/mm Al. A method of sealing a tooth canal, includes providing a canal in a tooth sealing the canal with this root canal sealing dental filling composition.

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