A thin, flexible, bilayer or multi-layer film which when applied to teeth surfaces adheres and delivers an active compound to the underlying surface and erodes at a predetermined rate. The amount of time that the active agent remains in contact with the teeth surfaces is controlled by the composition of backing layer of the composite film. This erosion or residence time can be regulated one half hour to three hours, depending upon the desired therapeutic or cosmetic application.
ERODIBLE FILM FOR TREATING THE SURFACES OF TEETH

[0001] This application is a continuation-in-part and is based on and claims priority from U.S. patent application Ser. No. 09/931,319, filed Aug. 16, 2001 and is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] This invention relates to the cosmetic or therapeutic treatment of teeth, and more specifically to an adherent, erodible film that provides an active ingredient to teeth surfaces for a prolonged and controlled period of time.

BACKGROUND OF THE INVENTION

[0003] A tooth is composed of a protective, hard enamel outer layer and an inner dentin layer. The enamel layer is typically opaque white or slightly off-white in color. This layer is composed of hydroxyapatite mineral crystals and is somewhat porous, allowing staining agents and discoloring substances to permeate the enamel and discolor teeth. In particular, certain foods, tobacco products, and beverages such as tea and coffee tend to stain teeth. These substances accumulate on the surface and form a film on the teeth, and will then permeate into the enamel layer. This problem occurs over many years, imparting a noticeable discoloration of the enamel layer.

[0004] There have been numerous methods in the prior art relating to teeth whitening, including brushing the teeth using dentifrices containing an effective oxidizing agent such as peroxide. These types of compositions are disclosed in U.S. Pat. No. 5,256,402. More recently, several over-the-counter teeth whitening systems have become available and have gained in popularity as an alternative cosmetic treatment to teeth whitening procedures conducted by a professional. One such product is comprised of a thin strip of plastic film that has a tooth whitening composition applied to the surface as described in U.S. Pat. Nos. 5,894,017, 5,891,453 and 6,045,811. In addition, U.S. Pat No. 6,419,906 B1 describes a flexible film which when applied to stained teeth is hydrated by saliva and is effective in such form to whiten teeth. The film comprises an anhydrous water hydratable ethylene oxide polymer matrix containing a solid peroxide whitening agent whereby, upon placing and positioning on stained teeth, the peroxide is solubilized and activated by the saliva present in the oral cavity. These aforementioned systems produce a whitening effect when applied to stained teeth; however, the strips must be removed after a specified period of time. U.S. patent application Ser. No. 09/931,319 teaches the administration of pharmaceutically active compounds using a multi-layered mucoadhesive erodible drug delivery device. Although this reference relates to an oral pharmaceutical application unrelated to teeth whitening, one important teaching is that the length of time the device remains on the mucosal surface before complete erosion, the “residence time”, is easily modulated by alterations of the backing layer. It is this teaching that will be utilized and adapted to the present invention relating to an erodible tooth-whitening strip. In the area of cosmetic dentistry, there is an ongoing need to improve the whitening efficiency and to provide more user-friendly over-the-counter products.

SUMMARY OF THE INVENTION

[0005] One object of the present invention is to provide a novel, cost-effective, erodible, layered device that adheres to the moist surfaces of teeth and delivers an active agent for a controlled period of time. Another object of the present invention is to provide a convenient, user-friendly, erodible, layered device that adheres to the moist teeth surfaces and delivers a tooth whitening agent to the underlying stained surfaces. A further object of this invention is to provide a tooth whitening device that is easily applied without breaking or leaving any unwanted residue on the hands. A further object of the present invention is to provide a flexible, layered device that conforms and adheres intimately and securely to the entire tooth surface, minimizing the exposure of any excess whitening agent to the surrounding gums as found with other competitive products.

[0006] The composition of the bi-layered and multi-layered devices consists of an adhesive, water soluble, polymeric layer containing a tooth whitening agent or other active compound and a coated, erodible backing layer that controls the desired residence time. Since the devices of the current invention can provide a longer contact time with a stained tooth surface before eroding, it is expected that lower and safer amounts of whitening agents can be used to accomplish similar or superior results than attained by other commercial products.

[0007] An important aspect of the present invention is an erodible multilayered strip comprising at least two layers, a first layer comprises a water soluble polymer or combination of polymers that adheres to moist enamel surfaces. A second layer is water erodible and controls the residence time that the strip remains adherent to the enamel surface. This erodible strip is preferably shaped to conform to an individual tooth or a row of teeth.

[0008] An important embodiment of the present invention involves erodible adhesive a mucoadhesive, erodible multilayered device comprising a first, water-soluble adhesive layer to be placed in contact with a mucosal surface and a second, water-erodible non-adhesive backing layer that controls residence time of the device. The first layer preferably comprises a tooth-whitening agent, at least one water-soluble film-forming polymer in combination with at least one mucoadhesive polymer; and said second, water-erodible non-adhesive backing layer comprises a precast film containing at least one of hydroxypropyl methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, and ethylene oxide-propylene oxide co-polymer, said backing layer being coated with at least one hydrophobic polymer, alone or in combination with at least one hydrophilic polymer, such that the backing layer is bioerodible.

[0009] An important aspect of the present invention is a mucoadhesive, erodible multilayered device comprising a first, water-soluble adhesive layer to be placed in contact with a mucosal surface and a second, water-erodible non-adhesive backing layer that controls residence time of the device. The first layer comprises a tooth-whitening agent (most preferably carbamide peroxide), at least one water-soluble film-forming polymer in combination with at least one mucoadhesive polymer. Said second, water-erodible non-adhesive backing layer comprises a precast film containing at least one of hydroxypropyl methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, and ethylene oxide-propylene oxide co-polymer. This backing layer
is coated with at least one hydrophobic polymer, alone or in combination with at least one hydrophilic polymer, such that the backing layer is bioerodible. The second water-erodible non-adhesive backing layer acts as a casting and support surface on which the adhesive layer is prepared. It preferably, and comprises a premade film of hydroxypropyl methyl cellulose in combination with a coating consisting of at least one hydrophobic polymer selected from the family of quaternary ammonium acrylate/methacrylate co-polymers, (Eudragit RS) ethyl cellulose and methyl cellulose, alone or in combination with at least one hydrophilic polymer, selected from the group consisting of polyvinyl pyrrolidone, hydroxypropyl methyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and polyvinyl alcohol.

**DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT**

**[0010]** In the present invention, a unique, erodible, layered device that adheres to tooth enamel surfaces is provided. The device is most applicable for the cosmetic treatment of stained teeth, by delivering a whitening agent or combination of agents thereof for a controlled period of time. The device can also be used for the delivery of fluoride and phosphates for the preventive treatment of caries and tartar accumulation, respectively.

**[0011]** The device initially adheres to a moist tooth surface due to the hydration and partial solubilization of the water soluble polymer layer. The whitening agent that is dispersed throughout this polymeric layer is then activated as it comes in contact with saliva and is released to the underlying surface. The erosion rate of the device is controlled by the coated backing layer, which affects the amount of time the whitening agent remains in contact with the enamel surface. The main purpose of the backing layer is to slow down the dissolution of the water-soluble polymeric layer containing a whitening agent, and therefore maximizing the direct contact time and unidirectional delivery to the tooth surface. The composition of the backing layer is easily adjusted to provide variable erosion rates from one half hour to several hours. The layered device is essentially totally erodible, and therefore does not require removal after the appropriate treatment time.

**[0012]** The Residence Time as defined above is difficult to quantitatively ascertain. One visual method is to apply the layered device to the teeth surface and periodically observe the covered surface using a mirror and assess approximately how much residue remains on the surface. Typically, as the backing layer erodes away at a predetermined rate, the adhesive swells and starts to dissolve and fall off the teeth surface. The actual residence time on each surface is controlled primarily by the flow of saliva to the surface and any friction created by interaction with the internal surface of the lips.

**[0013]** The polymeric coating layer that adheres to the tooth enamel is composed of one or more adhesive polymers, an appropriate whitening agent and a plasticizer. This coating may also contain an antioxidant, a preservative and a taste-masking flavor.

**[0014]** The adhesive polymers can be any water soluble, FDA approved polymer for oral applications that sticks to an enamel surface when in contact with a moist tooth surface. The adhesive polymers may comprise hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxyethylmethyl cellulose, sodium carboxymethyl cellulose, polyvinyl pyrrolidone, polyvinyl alcohol, polyethylene glycol, polyacrylic acid, polyethylene oxide, alone or in combination thereof. The preferred adhesive polymers are hydroxyethyl cellulose and polyvinyl pyrrolidone since they exhibit rapid and effective adhesion to enamel when in contact with a moist tooth surface.

**[0015]** The molecular weight of the adhesive polymer is also important, since it must be large enough so that an integral film can form, but not so large that immediate interfacial solubilization and adhesion to the enamel surface is impaired. Typical average molecular weights range between 50,000 and 1,500,000 Daltons, and preferably between 50,000 and 500,000.

**[0016]** The whitening agents suitable for the practice of the present invention include peroxides, metal chlorites, perborates, percarbonates, peroxyacids, persulfates, alone or in combination thereof. Suitable peroxide compounds include hydrogen peroxide, carbamide peroxide, calcium peroxide, and mixtures thereof. The preferred peroxide is carbamide peroxide. Suitable metal chlorites include calcium chlorite, barium chlorite, magnesium chlorite, lithium chlorite, sodium chlorite, and potassium chlorite. The preferred chlorite is sodium chlorite. A preferred percarbonate is sodium percarbonate, and the preferred persulfates are oxones.

**[0017]** The rate at which the whitening agent is solubilized and subsequently released to a tooth surface is controlled by varying the film thickness, polymer properties such as structure and molecular weight, type and properties of the whitening agent and the concentration of the whitening agent. The concentration of the whitening agent typically varies from about 0.1% to about 30% by weight of the total layered device, and preferably from about 0.5% to about 20% by weight.

**[0018]** A plasticizer useful for purposes of the present invention is selected from glycols such as propylene glycol, polyethylene glycol, polyhydric alcohols such as glycerin and sorbitol and glycerol esters such as glycerol triacetate. The plasticizer comprises about 0.2% to about 30% by weight of the film of the present invention and preferably about 0.5% to about 10% by weight.

**[0019]** Glycerin and propylene glycol are the preferred plasticizers for use in the present invention as well as polyethylene glycol. The preferred molecular weights for polyethylene glycol are in the range of 200-600 Daltons.

**[0020]** A colorant or opacifier can be incorporated in the adhesive layer or any of the layers of this device for use as an appearance enhancer. The colorant or opacifier comprises about 0.01% to about 10% by weight of the film of the present invention and preferably about 0.03% to about 1% by weight. Colors and opacifiers may also be used to help distinguish the non-adhesive backing layer from the enamel adhering layer. Some opacifiers include titanium dioxide, zinc oxide, zinc stearate and other materials.

**[0021]** In addition to the incorporation of whitening agents, a plasticizer, and colorants, there may also be included in the adhesive film matrix a minor amount, e.g., 0.01 to 2% by weight, of ingredients such as preservatives, antioxidants, and flavors.
The backing layer solution is composed of a mixture of a hydrophobic polymer, such as ethyl cellulose, methyl cellulose, propyl cellulose or other related polymers and copolymers, anionic, cationic and neutral polymers and copolymers of methyl methacrylate under the trade name EUDRAGIT®, and a water soluble polymer such as polyvinyl pyrrolidone, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl alcohol or any other water soluble polymer that can be completely dissolved in a hydrophilic organic solvent. The ratio of the hydrophobic to hydrophilic polymer is adjusted to increase or decrease the desired residence time that the device remains on the teeth before complete erosion. The ratio of hydrophobic to hydrophilic polymer ranges from 0.5:1 to 10:1 by weight, and preferably 1.5:1 to 3:1 by weight.

The backing layer solution may also contain a plasticizing agent, such as propylene glycol, polyethylene glycol, or glycine, in a small amount, 0.1 to 2.0% by weight, in order to improve the flexibility and conformability of the resultant layered film and to adjust the erosion rate of the device. Colors and opacifiers may also be added to help distinguish the non-adhesive backing layer from the enamel adhering layer.

Once dissolved, these solutions (adhesive and backing) are cast and processed into a thin film by techniques known in the art, such as by film dipping, film coating, film casting, spin coating, or spray drying. These films are produced on an appropriate support at the desired thickness and dried using an oven. The primary support can be a polymer-coated paper, Mylar or any other appropriate non-deformable and impervious surface. The preferable primary support is coated paper. The primary support’s casting surface must hold the film dimensionally stable during the coating and drying processes, but allow the resulting composite film to release when desired. The actual casting surface for these solutions may be the primary support or another layer of the device being produced, such as the precast film layer or a freshly cast adhesive or backing layer. The amount of coating solutions applied, using a suitable doctor blade or lab coater apparatus, ranges between 0.01 to 1.5 mm, and most preferably between 0.05 and 0.4 mm for the backing layer and between 0.8 and 1.3 mm for the adhesive layer. The amount of solids present in the coating solutions, the resulting solution viscosity and coating thickness applied determine the amount of coating film to be deposited on the casting surface.

The final layered device will consist of an adhesive layer and a hydrophobic layer with or without a precast hydroxypropylmethyl cellulose (HPMC) film in-between. A precast water soluble film between the adhesive and backing layers will typically provide a longer residence time on the teeth. Several methods of forming this device are now provided herein.

In one embodiment, the adhesive layer is formed on an appropriate primary support. In a separate operation, the backing layer is formed on a water soluble, polymeric precoat film of HPMC. The two films are then laminated, with the hydrophobic layer either on the outside or in the middle of the final composite film, using an appropriate binding solution such as polyvinylpyrrolidone dissolved in a water/ethanol mixture. This multi-layered film can be either peeled away from the primary support and cut into the desired shape or cut with the primary support still attached.

In another embodiment, the backing layer is formed on an appropriate primary support. A precast film of HPMC is then laminated to the backing layer using binding solution consisting of polyvinylpyrrolidone dissolved in a water/ethanol mixture. Then a distinct binding layer, typically composed of polyvinylpyrrolidone is formed on top of the HPMC precast film. Finally, the adhesive layer is formed on top of the binding layer. This resulting multi-layer film is then further processed as outlined above.

In a preferred embodiment, the adhesive layer is formed on an appropriate primary support by the casting methods previously described. The backing layer is then formed directly on top of the adhesive layer. This two-layer film is then further processed as outlined above.

In another preferred embodiment, the backing layer is formed on an appropriate primary support by the casting methods previously described. The adhesive layer is then formed directly on top of the backing layer and the resulting bilayered product is further processed as outlined above.

The thicknesses of each layer will affect the residence time of the device. The hydrophobic layer composition and thickness are the most important parameters in controlling the residence time. However, inclusion of the water soluble, polymeric precast film as one of the layers of the device will also increase the residence time, since the overall thickness of the device is increased.

The total thickness of the device is also an important consideration in regards to user acceptance. A very thick device becomes more noticeable with respect to “mouth feel”, and may cause the user to discontinue its use prematurely, thus compromising efficacy.

The total thickness of the device will also affect its ability to conform and adhere to teeth in an efficient manner. Typically, thin films are preferred since they can be easily applied and bent around the teeth, minimizing the amount of unattached area in the form of edges and corners that could cause the film to be accidentally pulled off the teeth. However, if the film is too thin, it will begin to lose tensile strength and rip during its application.

With respect to the individual layers of the composite film, the thickness of the adhesive layer is between 50μ and 300μ, and more preferably between 60μ and 140μ. The thickness of the backing layer is between 50μ and 300μ, and more preferably between 60μ and 100μ. The thickness of the precast layer if used to produce a multilayered device is between 25μ and 200μ, and more preferably between 50μ and 100μ. The overall thickness of the device is between 75μ and 500μ, and more preferably between 125μ and 300μ.

EXAMPLE 1

A 180.0 gram batch of placebo adhesive solution was prepared using 10.0 grams hydroxyethyl cellulose (Natrosol 2508 NF, Hercules), 10.0 grams polyvinyl pyrrolidone (PVP, Povidone P-1416; Spectrum), 0.65 grams sodium benzoate (Spectrum), 0.65 grams propylene glycol (Spectrum), and 158.7 grams deionized and 0.22μ-filtered water. This solution was used in Example 11 below.
EXAMPLE 2
[0035] A 29.87 gram batch of active adhesive solution was prepared using 4.37 grams hydroxyethyl cellulose (Natrosol 250L NF; Hercules), 1.80 grams PVP (Povidone P-1416; Spectrum), 0.09 grams sodium benzoate (Spectrum), 0.09 grams propylene glycol (Spectrum), 2.70 grams carboxymethyl cellulose (Spectrum), and 20.82 grams deionized and 0.22μF-filtered water. This solution was used in Examples 12 and 13 below.

EXAMPLE 3
[0036] A 25.94 gram batch of active adhesive solution was prepared using 3.51 grams hydroxyethyl cellulose (Natrosol 250L NF; Hercules), 1.66 grams PVP (Povidone P-1416; Spectrum), 0.08 grams sodium benzoate (Spectrum), 0.08 grams propylene glycol (Spectrum), 2.49 grams carboxymethyl cellulose (Spectrum), and 18.12 grams deionized and 0.22μF-filtered water. This solution was used in Examples 14 and 15 below.

EXAMPLE 4
[0037] A 46.84 gram batch of active adhesive solution was prepared using 2.70 grams hydroxyethyl cellulose (Natrosol 250L NF; Hercules), 1.35 grams PVP (Povidone P-1416; Spectrum), 0.15 grams sodium benzoate (Spectrum), 0.15 grams propylene glycol (Spectrum), 2.70 grams carboxymethyl cellulose (Spectrum), 1.95 grams sodium alginlate, and 37.84 grams deionized and 0.22μF-filtered water. This solution was used in Examples 16 and 17 below.

EXAMPLE 5
[0038] A 19.0 gm batch of backing solution was prepared using 2.0 grams of ethyl cellulose (Ethocel Premium Std 7; Dow Chemical), 1.0 grams of HPMC (Methocel E5 Prem LV; Dow Chemical), 1.0 gram Adams Extract Red Food Color, and 15.0 grams ethanol (190 proof; USP; Spectrum). This backing solution was used in Examples 11, 15, and 18 below.

EXAMPLE 6
[0039] A 16.5 gram batch of backing solution was prepared using 1.1 grams of ethyl cellulose, 1.1 grams of HPMC, 0.9 grams Adams Extract Red Food Color, and 13.4 grams ethanol (190 proof, USP; Spectrum). This backing solution was used to make Examples 16 and 17 below.

EXAMPLE 7
[0040] A 19.8 gram batch of backing solution was prepared using 2.2 grams of ethyl cellulose, 1.1 grams of HPMC, and 16.5 grams ethanol (190 proof, USP; Spectrum). This backing solution was used to make Examples 12, 13, 19, and 20 below.

EXAMPLE 8
[0041] A 25.2 gram batch of backing solution was prepared using 1.8 grams of ethyl cellulose, 1.8 grams of HPMC, and 21.6 grams ethanol (190 proof, USP; Spectrum). This backing solution was used to make Examples 21 and 22 below.

EXAMPLE 9
[0042] A 52.7 gram batch of laminating solution was prepared using 6.32 grams PVP (P1416; Spectrum), 23.19 grams ethanol (190 proof, USP; Spectrum), and 23.19 grams deionized and 0.22μF-filtered water.

EXAMPLE 10
[0043] The precast HPMC film used in several embodiments of this device was typically a 100μ thick sheet called EM1100 from Polymer Films. In some embodiments, it was stretched on a paper-and-foil frame of a Werner Mathis AG Lab Coater, type LT; and a backing solution selected from Examples 5-8 was poured on top and doctor-bladed at a 0.25 mm setting, then dried in the oven section of the Lab Coater.

EXAMPLE 11
[0044] A composite device was made by doctor-blading the adhesive solution of Example 1 into a film using the Lab Coater. The casting was performed on a polymer-coated paper from Fortifiber, which was put on the paper and foil frame of the Lab Coater, with a doctor blade setting of 1.76 mm. The film was automatically dried in the oven portion of the Lab Coater, and a smooth, integral layer of deposited, adhesive polymer resulted. Then, separately, a layer of backing solution from Example 5 was doctor-bladed on top of the precast HPMC film (Example 10) using a 0.25 mm setting. The two films were then laminated together using the laminating solution described in Example 9 and pressure from a roller, followed by drying in the Lab Coater oven. The film was cut either before or after removal from the coated paper and upon application to a moist tooth surface, the film stuck well.

EXAMPLE 12
[0045] A composite device was made as in Example 11, except using the adhesive of Example 2, with doctor-blade setting of 1.00 mm, and the backing solution of Example 7. After cutting and removal from the casting coated paper, the resulting film also stuck well to teeth.

EXAMPLE 13
[0046] Another composite device was made by putting a backing layer of 2:1 ethyl cellulose to HPMC as described in Example 7 on polymer-coated paper (from Fortifiber) and then putting a layer of whitening adhesive (Example 2) on top of it. The backing layer was doctor-bladed at a 0.43 mm setting and the adhesive was doctor-bladed at a setting of 1.30 mm. This film after removal from the paper and cutting, stuck immediately and firmly to teeth, conformed extremely well, and eroded away without notice.

EXAMPLE 14
[0047] A composite device composed of only an adhesive layer was made using the process outlined in Example 11, except the adhesive of Example 3 was used and with a doctor blade setting of 1.30 mm. A test was done to determine the whitening efficacy of this adhesive layer alone as compared to the competitive product Crest Whitestrips. Both products were dampened and pressed onto a coffee-stained white cup. They were removed after 16 hours. The amount of whitening was compared and ranked by eight individuals who did not know which device did which whitening. The results shown below indicate that the adhesive layer containing a whitening agent is as effective if not better than one competitive product.
[0048] Adhesive only: 5 firsts, 1 tie, and 2 seconds; relative average score = 1.38

[0049] Crest White Strip: 2 first, 1 tie, and 5 seconds; relative average score = 1.75

EXAMPLE 15

[0050] A composite device was made by putting a layer of active adhesive from Example 3 on a polymer-coated paper (Fortifiber) and then putting a layer of backing solution from Example 5 on top of it. The adhesive was doctor-bladed at settings of 1.30 mm. The backing layer was spread thinly onto the surface of the dried adhesive film using a spatula and then dried. This resulting film after removal from the coated paper stuck well to the teeth.

EXAMPLE 16

[0051] A composite device was made as in Example 15, except using the adhesive of Example 4 and with a doctor blade setting of 1.30 mm and the backing solution of Example 6 with a doctor blade setting of 0.25 mm. A strip of this film after removal from the surface of the coated paper and cutting, lasted about 1½ hours on the front teeth.

EXAMPLE 17

[0052] A composite device was made as in Example 15, except using the adhesive of Example 4 and the backing solution of Example 6. A strip of this film after removal from the surface of the coated paper and cutting, lasted about 1 hour on the front teeth.

EXAMPLE 18

[0053] A composite device was made as in Example 11, except using the adhesive of Example 3 without the tooth whitening agent, carbamide peroxide, and doctor blade settings of 1.30 mm. After processing, this placebo film visually seemed similar to the active films and upon removal from the coated paper and cutting, stuck comparably to the teeth.

EXAMPLE 19

[0054] A composite device was made as in Example 11, except using the adhesive of Example 4, a doctor blade setting of 1.30 mm, and the backing solution of Example 7.

EXAMPLE 20

[0055] A composite device was made as in Example 15, except using the adhesive of Example 4, with a doctor blade setting of 1.30 mm, and the backing solution of Example 7. The resulting film after removal from the coated paper and cutting, lasted more than ½ hour on the front teeth.

EXAMPLE 21

[0056] A composite device was made as in Example 11, except using the adhesive of Example 4, with doctor blade setting of 1.30 mm, and the backing solution of Example 8. The resulting film after removal from the coated paper and cutting, lasted about 1½ hours on the front teeth.

EXAMPLE 22

[0057] A composite device was made as in Example 15, except using the adhesive of Example 4, with doctor blade setting of 1.30 mm, and the backing solution of Example 8. The resulting film, after removal from the coated paper and cutting, lasted about 1 hour on the front teeth.

[0058] Those skilled in the art will recognize that, while specific embodiments and examples have been described, various modifications and changes may be made without departing from the scope and spirit of this invention.

1. An erodable strip comprising at least two layers, wherein one layer comprises a water soluble polymer or combination of polymers that adheres to moist enamel surfaces; and a second layer which is water erodable and controls the residence time that the strip remains adhered to the enamel surface.

2. The erodable strip of claim 1 being geometrically shaped as a strip to conform to an individual tooth or a row of teeth.

3. The strip of claim 2 wherein said water soluble polymer is at least one of polyvinyl pyrrolidone, polyvinyl alcohol, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, polyethylene oxide, polyethylene glycol, and polyacrylic acid.

4. The strip of claim 2 wherein said first layer comprises a water soluble polymer or combination of polymers thereof and at least one tooth-whitening agent.

5. The strip of claim 4 wherein said tooth whitening agent is at least one selected from the group consisting of peroxides, metal chlorites, perborates, percarbonates, peroxycarbonates, and persulfates.

6. The strip of claim 4 wherein said tooth whitening agent is carbamide peroxide.

7. The strip of claim 2 wherein said second layer comprises a mixture of hydrophobic and water soluble polymers, consisting of at least one of polyvinyl pyrrolidone, polyvinyl alcohol, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, and polyvinyl alcohol.

8. The strip of claim 7 wherein said second layer comprises a mixture of hydrophobic and water soluble polymers at a ratio of 0.5:1 to 10:1 by weight.

9. The strip of claim 8 where the ratio is 1:5:1 to 3:1 by weight.

10. A strip film of claim 1 comprising a first layer consisting of a water soluble polymer or combination of polymers that adheres to moist enamel surfaces, a laminated middle layer comprising a precast film of a water soluble polymer, and a water erodal backing layer that controls the residence time that the film remains adhered to a tooth surface.

11. The strip of claim 10 defined as is geometrically shaped to conform to an individual tooth or a row of teeth.

12. The strip of claim 10 wherein the precast water soluble polymer is hydroxypropylmethyl cellulose.

13. The strip of claim 10 wherein said first layer comprises at least one water soluble polymer and at least one tooth whitening agent.

14. The strip of claim 10 wherein a laminating solution used to effectively bind the middle layer to the other two layers is composed of at least one water soluble polymer dissolved in alcohol, water, or an aqueous alcohol mixture.
15. The strip of claims 4 or 13 wherein said whitening agent is from 0.1% to 30% by weight of the strip.

16. The strip of claims 4 or 13 wherein said whitening agent is from 0.5% to 20% by weight.

17. The erodible teeth whitening strip of claims 2 or 11 defined further as containing propylene glycol, polyethylene glycol, glycerin, sorbitol, or glycerol acetate plasticizer at a concentration of 0.2% to 30% by weight.

18. The strip of claim 17 where the concentration is 0.5 to 10% by weight.

19. The erodible teeth whitening strip of claims 2 or 11 defined further as containing a titanium dioxide, zinc oxide or zincium silicate colorant or opacifier as an appearance enhancer.

20. The strip of claim 19 where the appearance enhancer is at a concentration of 0.01% to 10% by weight.

21. The strip of claim 19 where the appearance enhancer is 0.03% to 1% by weight.

22. The erodible, teeth whitening strip of claims 2 and 11 defined further as containing at least one of a preservative, antioxidant, or flavor.

23. The strip of claim 19 where the appearance enhancer is at a concentration of 0.01% to 2% by weight.

24. The strip of claim 3 wherein said polymer is in a molecular weight range of between 25,000 and 1,500,000 Daltons.

25. The strip of claim 3 wherein said polymer is in a molecular weight range of 30,000 and 500,000 Daltons.

26. The strip of claims 2 or 11 wherein said first layer comprises at least one water soluble polymer and at least one compound that dissociates to release fluoride ions for the prevention of caries.

27. The strip of claims 2 or 11 wherein said first layer comprises at least one water soluble polymer and at least one phosphate compound for tartar control.

28. The strip of claims 2 or 11 wherein said first layer comprises at least one water soluble polymer and at least one ingredient that can cosmetically alters the appearance of teeth.

29. A mucoadhesive, erodible multi-layered device comprising a first, water-soluble adhesive layer to be placed in contact with a mucosal surface and a second, water-erodible non-adhesive backing layer that controls residence time of the device;

wherein said first layer comprises a tooth-whitening agent, at least one water-soluble film-forming polymer in combination with at least one mucoadhesive polymer; and said second, water-erodible non-adhesive backing layer comprises a precast film containing at least one of hydroxypropyl methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, and ethylene oxide-propylene oxide co-polymer, said backing layer being coated with at least one hydrophobic polymer, alone or in combination with at least one hydrophilic polymer, such that the backing layer is bioerodible.

30. The mucoadhesive, erodible multi-layered device of claim 29, wherein said second water-erodible non-adhesive backing layer acts as a casting and support surface on which the adhesive layer is prepared, and comprises a premade film of hydroxypropyl methyl cellulose in combination with a coating consisting of at least one hydrophobic polymer selected from the family of quaternary ammonium acrylate/methacrylate co-polymers, (Eudragit RS) ethyl cellulose and methyl cellulose, alone or in combination with at least one hydrophilic polymer, selected from the group consisting of polyvinyl pyrrolidone, hydroxypropyl methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and polyvinyl alcohol.

31. The device of claim 29 where the tooth-whitening agent is carbamide peroxide.

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