AN ORAL CARE COMPOSITION COMPRISING A ZINC OXIDE ENTRAINED IN A FILM

~~STABILIZATION OF ZINC OXIDE FILM IN ORAL COMPOSITIONS~~

BACKGROUND

[0001] This application relates to oral and personal care compositions, and more particularly to compositions comprising a film entrained in a carrier, in which the film includes zinc oxide. Such compositions include, for example, dentifrices.

[0002] The aesthetic appeal of such compositions is important, and can have significant effects on consumer acceptance and usage. Aesthetic effects have been acknowledged to play an important role in consumer acceptance of many products. Although such products have met with consumer approval, the art seeks to further improve the aesthetic effects as well as the cosmetic and therapeutic benefits of these products. Indeed, many such compositions known in the art are deficient in one or more attributes.

[0003] Compositions for enhancing health, hygiene or appearance, such as oral care compositions, skin care compositions and hair care compositions, are used by millions of people. These compositions are used for a wide variety of purposes, including for enhancing personal health, hygiene, and appearance, as well as for preventing or treating a variety of diseases and other conditions in humans and in animals.

[0004] The formulation of such compositions presents a number of challenges. They must be pharmaceutically and/or cosmetically acceptable for their intended use. Compositions that contain therapeutic active materials preferably deliver the active at effective levels, avoiding undue chemical degradation. Similarly, compositions containing cosmetically functional materials must deliver the material to, e.g., the oral cavity, skin or hair at effective levels under the conditions that they are typically used by the consumer.

[0005] Water-soluble films for oral administration of therapeutic agents are well known in the art. It is also known in the art to use such films for administering a breath freshening agent, e.g., menthol. The known films for administering breath freshening agents and/or active pharmaceutical agents are generally comprised of at least one water-soluble polymer suitable for human consumption and at least one compound that enhances the wettability of the water-soluble polymer, typically selected from polyalcohols, surfactants and plasticizers. For example, U.S. Pat. No. 5,948,430~~, the disclosure of which is incorporated by~~

reference herein in its entirety, describes a monolayer film that can be adhered to the oral cavity to release a pharmaceutically or cosmetically active ingredient, wherein the film comprises at least one water-soluble polymer; at least one member selected from the group consisting of a polyalcohol, a surfactant and a plasticizer; at least one cosmetic or pharmaceutically active ingredient; and a flavoring agent.

[0006] U.S. Pat. No. 5,700,478, the disclosure of which is incorporated by reference herein in its entirety, describes a laminated device for controlled release of a substance within a mucosa-lined body cavity including a water-soluble adhesive layer comprised of a water-soluble polymer and a water-soluble plasticizer, and a water-soluble polymer layer. This patent teaches a multiple layer laminate that dissolves relatively slowly for controlled or sustained release of a substance.

[0007] U.S. Pat. No. 4,900,552, the disclosure of which is incorporated by reference herein in its entirety, describes a trilaminate film suitable for prolonged and sustained delivery of an active ingredient in a buccal cavity. The trilaminate includes a hydratable muco-adhesive base layer; a non-adhesive reservoir layer; and a water-impermeable barrier sandwiched between and bonded to the base layer and the reservoir layer. This patent discloses slowly disintegrating films for prolonged or sustained release of a substance.

[0008] U.S. Pat. No. 5,047,244, the disclosure of which is incorporated by reference herein in its entirety, discloses a therapeutic dosage form comprising an anhydrous but hydratable monolithic polymer matrix that contains amorphous fumed silica as well as a therapeutic agent, and a water-insoluble barrier layer secured to the polymer matrix and defining a non-adhesive face. This patent does not disclose rapidly disintegrating films, but instead contemplates compositions that are capable of providing improved availability of therapeutic agents from a controlled release muco-adhesive carrier system.

[0009] U.S. Patent No. 6,669,929, and U.S. Patent Application Publication No. 2003/0053962, the disclosures of each of which are incorporated by reference herein in their entirety, disclose film forming agents useful in oral care compositions. The films dissolve in the mouth and release functional components, typically flavorants.

[0010] It is known to incorporate flavorants, colorants, and some active components in films that dissolve in the oral cavity. These films are used either by themselves as breath freshening strips, teeth whitening strips, or as polymer flakes dispersed throughout an oral care

herein. ~~All references cited in the Description section of this specification are hereby incorporated by reference in their entirety.~~

[0022] The description and specific examples, while indicating embodiments of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention. Recitation of multiple embodiments having stated features is not intended to exclude other embodiments having additional features, or other embodiments incorporating different combinations of the stated features. Specific Examples are provided for illustrative purposes of how to make, use and practice the compositions and methods of this invention and, unless explicitly stated to recite activities that have been done (i.e., using the past tense), are not intended to be a representation that given embodiments of this invention have, or have not, been performed.

[0023] As used herein, the words "preferred" and "preferably" refer to embodiments of the invention that afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the invention. As used herein, the word "include," and its variants, is intended to be non-limiting, such that recitation of items in a list is not to the exclusion of other like items that may also be useful in the materials, compositions, devices, and methods of this invention. In a similar manner, the description of certain advantages or disadvantages of known materials and methods is not intended to limit the scope of the embodiments to their exclusion. Indeed, certain embodiments may include one or more known materials or methods, without suffering from the disadvantages discussed herein.

[0024] As used herein, the term "comprising" means that other steps and other components that do not affect the end result may be utilized. The term "comprising" encompasses the expressions "consisting of," and "consisting essentially of." The expression "effective amount," as used herein denotes an amount of a compound or composition sufficient to significantly induce a positive benefit, preferably an oral health benefit, but low enough to avoid serious side effects, i.e., to provide a reasonable benefit to risk ratio, within the sound judgment of a person having ordinary skill in the art. The use of singular identifiers such as

polymers among those useful herein include polyvinylpyrrolidone, cross-linked polyvinyl pyrrolidone, polyvinylpyrrolidone-vinyl acetate copolymer, polyvinylalcohol, polyacrylic acid, poly acrylate polymer, cross-linked polyacrylate polymer, cross-linked polyacrylic acid (e.g, Carbopol®), polyethylene oxide, polyethylene glycol, poly vinylalkyl ether-maleic acid copolymer (such as Gantrez®) and carboxy vinyl polymer; natural gums such as sodium alginate, carrageenan, xantham gum, gum acacia, arabic gum, guar gum, pullulan, agar, chitin, chitosan, pectin, karaya gum, zein, hordein, gliadin, locust bean gum, tragacantha and other polysaccharides; starches such as maltodextrin, amylose, high amylose starch, corn starch, potato starch, rice starch, tapioca starch, pea starch, sweet potato starch, barley starch, wheat starch, waxy corn starch, modified starch (e.g. hydroxypropylated high amylose starch), dextrin, levan, elsinan and gluten; and proteins such as collagen, whey protein isolate, casein, milk protein, soy protein and gelatin.

[0033] Non-limiting examples of water dispersable and swellable polymers include modified starch, alginate esters, divalent or multivalent ion salts of alginates. Non-limiting examples of water insoluble polymers include polymers soluble in at least one organic solvent, such as cellulose acetate, cellulose nitrate, ethylene-vinyl acetate copolymers, vinyl acetate homopolymer, ethyl cellulose, butyl cellulose, isopropyl cellulose, shellac, silicone polymer (e.g. dimethylsilicone), PMMA (poly methyl methacrylate), cellulose acetate phthalate and natural or synthetic rubber; polymers insoluble in organic solvents, such as cellulose, polyethylene, polypropylene, polyesters, polyurethane and nylon.

[0034] The films useful in the various embodiments can be made in accordance with the methods described in U.S. Patent No. 6,669,929, and U.S. Patent Application Publication No. 2003/0053962~~, the disclosures of which are incorporated by reference herein in their entirety~~. The zinc oxide contained within the film can be incorporated into the film during film manufacture using techniques known in the art. A person having ordinary skill in the art will be capable of making the film containing the zinc oxide, using the guidelines provided herein.

[0035] The zinc oxide contained within the film provides a source of zinc ions. Zinc ions are derived from the zinc oxide present in the film in the dentifrice composition in an effective amount. An effective amount of zinc ions is defined as from at least 1000 ppm zinc ion, preferably 2,000 ppm to 15,000 ppm. More preferably, zinc ions are present in an amount from 3,000 ppm to 13,000 ppm and even more preferably from 4,000 ppm to 10,000 ppm. This

9. An oral care composition comprising:
a zinc oxide entrained in a film;
a sodium lauryl sulfate (SLS) present in an amount from 1.5% to 2.2% by weight; a betaine surfactant present in an amount from 0.1% to 0.5% by weight; and a polyethylene glycol present in an amount from 2% to 3% by weight.

10. The oral care composition of claim 9, wherein the polyethylene glycol is PEG-600.

11. Use of ~~A method of providing oral health benefits to an oral surface comprising contacting the oral surface with~~ an oral care composition according to any of claims 1 to 8 for the manufacture of a medicament for providing oral health benefits to an oral surface.