COMPOSITIONS AND METHODS FOR TREATING NAILS AND ADJACENT TISSUES

This application claims priority under 35 U.S.C. §119 and/or 365 to U.S. provisional application No. 60/116,595 filed in U.S. on Jan. 20, 1999; the entire content of which is hereby incorporated by reference.

FIELD OF THE INVENTION

The present invention relates to compositions and methods for use in treating nails and adjacent tissues.

BACKGROUND OF THE INVENTION

The fingernails and toenails of humans are composed of clear, horny cells of the epidermis, joined so as to form a solid, continuous plate upon the dorsal surface of the terminal phalanges. Each nail is closely adherent to the underlying corium, which is modified to form what is called the nail bed, or matrix. The body of the nail is the part that shows. The hidden part, in the nail groove, is called the root.

The nails grow in length by multiplication of the soft cells (corneocytes) in the stratum germinativum at the root. The cells are transformed into hard, dry scales, which unite to form a solid plate; and the nail, constantly receiving additions, slides forward over its bed and projects beyond the end of the finger.

Keratin fibrils found within the corneocytes provide strength and flexibility to the cells due to the presence of cysteine disulfide bridges, which are found at a level of about 9.4% by weight in the nail. In addition, the intercellular adhesive factors which hold corneocytes together also provide strength and flexibility. These intercellular adhesive factors are intercellular cement, desmosomes, and gap junctions and narrow junctions.

The nails often become brittle or damaged from a variety of exposures including washing and cleaning agents, organic solvents in nail polishes and nail polish removers, dehydration, bacterial or fungal infections, injuries and aging. As a result, a variety of approaches have been used to strengthen and harden nails, including the application of enamel coatings, lotions, oils and adhesives.

Numerous nail hardening or strengthening compositions have been marketed with varying results. In most cases, these compositions include ingredients that do not interact directly with the nail, but are protective coatings which are applied to the surface of the nail. There is a need for nail strengthening compositions that are capable of interacting with the nail to enhance nail strength without using organic solvents and other chemicals which can ultimately damage the nail.

Approaches in the use of traditional nail hardening agents that are applied as protective coating for the nail body have been described. For example, U.S. Pat. No. 5,508,027 discloses methods and compositions for strengthening nails (ungues) by the periodic application of synthetic gums of acrylic polymer films on the nail body. These acrylic polymer films are aqueous-based and avoid using the harmful organic solvents commonly found in other nail polish products. While this approach eliminates the use of harmful solvents, the composition must be applied from 1 to 5 times a day to 1 to 3 times a week over a period of at least a month to be effective.

U.S. Pat. Nos. 4,873,077 and 4,482,538 disclose preparations for strengthening nails by using hardener compositions. The compositions include a nitrocellulose-based lacquer and inert glass fibers or beads. The inert glass fibers or beads act as a reinforcement phase that increases the strength and wear resistance of the coatings of the nails relative to a conventional lacquer film alone. A limitation of this approach is that the compositions use organic solvents which can be detrimental to nail health, and the compositions do not increase the strength of the nail itself.

Nail hardening agents have been developed which interact with the nail body. For example, U.S. Pat. No. 5,785,959 discloses using a three part nail strengthening composition which penetrates and interacts with the nail and enhances the binding of water or lipids from the nail bed. This results in water retention within the nail, which reduces the brittleness of the nail resulting from decreased moisture content.

U.S. Pat. No. 4,919,920 discloses compositions and methods for hardening and strengthening the keratinized appendages of mammals by topically applying fluoride ions in an aqueous cosmetic vehicle. The use of fluoride ions simultaneously hardens and strengthens the nail. U.S. Pat. No. 5,478,551 discloses compositions and methods for strengthening nails by using a non-aqueous organic composition containing ammonium hexafluorophosphate to provide an effective amount of fluoride to the nail body. Both of these approaches can potentially form harmful acidic by-products, and the second approach uses organic solvents, both of which can damage the nail body and irritate the surrounding tissues.

It would be advantageous to provide compositions and methods of treating nails in humans (as well as other mammals) and surrounding tissues which avoid using organic solvents and which also avoid creating acidic by-products. The present invention provides such compositions and methods.

SUMMARY OF THE INVENTION

Compositions and methods for treating nails and adjacent tissues are disclosed. Formulations including the compositions and a suitable topical carrier are also disclosed. The compositions include non-interlinked particles of bioactive glass or glass-ceramic, optionally include an aqueous vehicle, and further optionally include a hydrophilic polymer. The methods involve applying an effective nail-enhancing amount of the composition to the nail body for a sufficient amount of time such that a layer of hydroxyapatite or other calcium phosphate crystals is formed on the nail and ions from the glass penetrate the layers of the nail to form hydroxyapatite crystals within the layers of the nail.

When the compositions are in the form of aqueous solutions, the methods involve soaking the nails in the solutions for a sufficient period of time to create a layer of hydroxyapatite or other calcium phosphate mineral on the nail and allows calcium and phosphate ions to penetrate through the porous outer surface of the nail into the body of the nail and form apatite or other calcium phosphate crystals. When the composition is in the form of a gel (i.e., includes a hydrophilic polymer), the compositions can be applied to the nail and can remain on the nail bed until the gel is wiped off. In one embodiment, the hydrophilic polymer includes a polymerizable group which is polymerized when the composition is applied to the nail bed to facilitate maintaining the composition in contact with the nail bed.

In one embodiment, the compositions can include additional components, such as antibiotics, antivirals, anti-fungal agents, biotin, collagen, amino acids, proteins, vitamins, penetration enhancers and/or permeation/binding agents, dyes, fragrances and other cosmetically useful additives. Bioactive glass also has anti-microbial properties.