

Soluble Keratin Peptide ingredient –

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a wound-healing agent which can include a peptide having an ionizable pendant group such as sulfonic acid which can be derived from an oxidized protein disulfide linkage. A preferred source of protein is keratin. One preferred source of keratin is hair. While hair is a preferred source of keratinous material, other keratinous materials such as animal hair, skin, beaks, hooves, feathers, and nails are also suitable for use in the present invention. The patient or a human donor are some preferred sources of hair, as hair from these sources is most likely to result in a non-antigenic wound-healing product, although animal hair may be acceptable for many individuals. In one method according to the present invention, hair is provided, preferably clean and unbleached. In another method, the hair is washed with Versa-Clean™ (Fisher Scientific, Pittsburgh, Pa.), rinsed with de-ionized water, and dried.

The powder obtained from one method is whitish to yellow in color and is completely soluble in water. Analysis of these samples has shown them to be Gaussian distributions of low molecular weight peptides, as shown in the chromatogram of FIG. 1. Elemental analysis has shown the carbon content to be between 38.39 and 41.59 weight percent; the hydrogen content to be between 5.74 and 6.16 weight percent; the nitrogen content to be between 15.19 and 15.89 weight percent; the oxygen content to be between 23.67 and 26.97 weight percent; and the sulfur content to be between 3.80 and 4.78 weight percent. Analysis of mass spectra shows a distribution of molecular weight species, centered at approximately 850 daltons.

The peptide provided by the present invention can be used in several applications. The **skin healing properties of the peptide can be used to promote healing, repair, and cell growth in keratinous tissue generally.** The peptide can be used to treat damaged skin and skin wounds including, for example, rashes, including diaper rash, burns including sunburn, cuts, abrasions, punctures, sores including bed sores, ulcers including diabetic ulcers and other skin injuries or irritations. The **peptide can also be used to treat aging, weakened or damaged skin, including, for example, wrinkled skin.** In one use, the keratinous tissue is damaged tissue located either externally or internally. In one example of use, an external wound can be treated by applying the peptide to the wound. In one method, the peptide is admixed with a cream, lotion, or gel before application to the skin. In another method, the peptide is added to a keratin hydrogel prior to application to the skin. A keratin hydrogel can be made according to, for example, U.S. patent application Ser. No. 08/979,456, filed Nov. 26, 1997, entitled KERATIN-BASED HYDROGEL FOR BIOMEDICAL APPLICATIONS AND METHOD OF PRODUCTION. In another method, the peptide can be added to a wound dressing prior to application. For example, the peptide can be added to a keratin sheet as described in U.S. patent application Ser. No. 08/979,526, filed Nov. 26, 1997, ENTITLED KERATIN-BASED SHEET MATERIAL FOR BIOMEDICAL APPLICATIONS AND METHOD OF PRODUCTION.

In another use of the invention, the peptide can be applied internally to damaged keratinous tissue lining the GI tract by orally administering the peptide. Examples of such damage can result from ulcers, colitis, or Crohn's disease.

The peptide can also be added as a cell growth stimulant to a tissue engineering scaffold such as the sheet described in U.S. patent application Ser. No. 09/198,998, filed Nov. 24, 1998, entitled METHOD OF CROSS-LINKING KERATIN-BASED FILMS, SHEETS, AND BULK MATERIALS. The peptide is believed suitable to speed repair of sun or weather damaged skin. The peptide can be mixed with a carrier lotion such as lanolin and applied to the skin. The peptide can also be added to cosmetics to impart a skin healing property to the cosmetic. Cosmetic bases are believed suitable for inclusion of peptides made according to the present invention.

EXPERIMENTAL RESULTS

Referring to the table in FIG. 2, cell studies were performed on **human skin keratinocytes, human dermal fibroblasts, and microvascular endothelial cells**, as indicated, to determine the effect of **the keratin peptide on proliferation of cells critical to the wound-healing process. Known growth factors for each cell line were used as positive controls.** The following concentrations of keratin peptide were used: 0 (control, media alone); 0.005; 0.01; 0.05; 0.1; 0.5; 1; 5; and 10 micrograms per milliliter. At day 5 of the study, the cells were analyzed using a technique that counts the number of cells.

The purpose of this study was to assess cell proliferation as a result of their exposure to the keratin peptide, relative to no exposure (media alone) and to known stimulants for each cell type, the "positive control." Exposure to media alone was considered the baseline of the study, so the average number of cells in the baseline cultures was subtracted out of the average number of cells in the cultures containing the soluble peptides and the positive control for each cell line. This process mathematically reduces the baseline to zero and everything else becomes relative to zero, as seen in the first column of data. These subtracted numbers are divided through by the average baseline value and become a percent above or below baseline. The numbers in the table represent the percent above baseline.

As can be seen from inspection of FIG. 2, **the keratin-derived peptide stimulated growth of the selected cell lines and compares favorably with the known growth factors for each cell line.** In particular, at 0.5 micrograms per milliliter of peptide, **skin keratinocytes grew over 28% percent more than with media alone**, and at 5 micrograms peptide per milliliter, **dermal fibroblasts grew over 12 percent more** relative to the baseline. At 0.05 micrograms of peptide per milliliter of media, micro-vascular endothelial cells grew more than 9 percent more than the media only baseline. Application of the keratin-derived peptide is thus believed to be useful as a wound-healing agent.

Numerous advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of reagents, concentrations, and step order, without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.