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Attorneys for Plaintiff,
CERTIFIED NUTRACEUTICALS, INC.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

CERTIFIED NUTRACEUTICALS, INC., a California Corporation,

Plaintiff,

vs.

NUTRAWISE, INC., dba YOUTHEORY, a California Corporation, DARREN RUDE, an individual, NEOCELL CORPORATION, a California Corporation, COLLAGEN M.D., INC, a California Corporation, AXE WELLNESS, a Tennessee Limited Liability Company, DR. VENESSA's FORMULAS, a Florida entity, an individual, IRIS TRADING, an entity form unknown, NUTRA FOOD INGREDIENTS, dba NUTRA COLLAGEN, a Michigan Limited Liability Company; MERCOLA.COM HEALTH RESOURCES, LLC, dba DR. MERCOLA, an Illinois Limited Liability Company; DR. JOSEPH MERCOLA, an individual; VESTA INGREDIENTS, INC., an Indiana Corporation; NUTRACEUTICAL CORPORATION, a Utah Corporation; NEW ENGLAND GREENS, LLC, dba VIBRANT HEALTH, a Connecticut Limited Liability Company;and DOES 1 through 10, inclusive,

Defendants.

CASE NO. **'17CV1403 MMAAGS**

COMPLAINT FOR:

PATENT INFRINGMENT
(35 U.S.C. § 271)

[DEMAND FOR A JURY TRIAL]

Plaintiff Certified Nutraceuticals, Inc. ("Certified Nutraceuticals" or "Plaintiff"), by and through its undersigned attorneys, submits this Complaint against Defendants as follows:

INTRODUCTION

1. Defendants are engaged in the manufacture, marketing and/or sale of certain products containing avian collagen, including without limitation, "Anti-Aging 3 Collagen"; KollaGenII-xsTM (collectively, the "Infringing Products"), which infringe on a number of patents held by Plaintiffs, or regarding which Plaintiff has exclusive rights, including, without limitation, U.S. Patent Nos. 6,025,327; 6,838,440; 6,323,319; and 8,344,106 (collectively, the "Patents").

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1338 (a) (federal question) which states in pertinent part that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . ." and that "[n]o State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents . . ." Here, Plaintiff asserts a federal cause of action for patent infringement as against all Defendants which places this action within the jurisdictional purview of this Court.

3. This Court has personal jurisdiction over each Defendant in this action because Defendants have, directly or through its intermediaries (including other distributors and retailers), developed, licensed, manufactured, shipped, distributed, offered for sale, sold, and advertised its products in the United States, the State of California and this district. Defendants have purposefully and voluntarily placed these products into the stream of commerce with the expectation that they will be purchased in this district.

4. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions which gave rise to the claim occurred in this district. *Allstar Marketing Group, LLC v. Your Store Online*, LLC, 666

F. Supp. 2d 1109, 1128 (C.D. Cal. 2009). Alternatively, venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(3).

PARTIES

5. Plaintiff Certified Nutraceuticals is a corporation organized and existing under the laws of the State of California, with its principal place of business listed as: 15045 Adams Drive, #1065, Pauma Valley, California 92061.

6. Defendant NUTRAWISE, INC is a California Corporation with its principal place of business in Orange County California.

7. Defendant DARREN RUDE, an individual who, on information and belief, resides in Orange County, California.

8. Defendant NEOCELL CORPORATION is a California Corporation with its principal place of business in Orange County California.

9. Defendant COLLAGEN M.D., INC is a California Corporation with its principal place of business in Orange County California.

10. Defendant AXE WELLNESS is a Tennessee Limited Liability Company.

11. Defendant DR. VENESSA's FORMULAS is a Florida entity form unknown.

12. Defendant IRIS TRADING, is an entity form unknown with its principal place of business in Florida.

13. Defendant NUTRA FOOD INGREDIENTS, dba NUTRA COLLAGEN, is a Michigan Limited Liability Company.

14. Defendant MERCOLA.COM HEALTH RESOURCES, LLC, dba DR. MERCOLA, is an Illinois Limited Liability Company.

15. Defendant DR. JOSEPH MERCOLA, an individual who, on information and belief, resides in the state of Illinois.

16. Defendant VESTA INGREDIENTS, INC., is an Indiana Corporation with its principal place of business in Indianapolis Indiana believed to be located at address commonly known as 5767 Thunderbird Road, Indianapolis, Indiana 46236.

17. Defendant NUTRACEUTICAL CORPORATION is a Utah Corporation conducting business at location commonly known as 1400 Kearns Boulevard, Park City, Utah 84060 with email domain name "www.nutraceutical.com".

18. Defendant NEW ENGLAND GREENS, LLC is a Connecticut Limited Liability Company conducting business at location commonly known as 99 Railroad St., Canaan, CT 06018 with email domain name "www.vibranthealth.com".

19. Plaintiff is ignorant of the true names and capacities of defendants sued herein as Does 1-10, inclusive, and therefore sued these defendants by such fictitious names. Plaintiff will amend this Complaint to allege their true names and capacities when ascertained. Plaintiff is informed and believes and thereon alleges that each of these fictitiously named defendants is responsible in some manner for the occurrences herein alleged, and that Plaintiff's injuries as herein alleged were proximately caused by the aforementioned defendants.

FACTUAL ALLEGATIONS

A. Plaintiff Certified Nutraceuticals

20. Certified Nutraceuticals is a world renowned and trusted industry leader in the development and manufacturing of nutritional ingredients. Certified Nutraceuticals' nutritional ingredients are sold worldwide to formulators of nutraceuticals and authentic dietary supplements.

21. Certified Nutraceuticals specializes in quality collagen nutritional ingredients as well as a broad range of cutting edge nutraceuticals that are recognized globally for cardiovascular, joint, skin, eye health and anti-aging support.

22. Certified Nutraceuticals pioneered the original invention of four Collagen Type II patents (U.S. Patent #8,344,106 B1) for dietary supplements and was the first to introduce Collagen Types I, II, and III food supplements to the market. Collagen is a complex structural protein, which provides strength and flexibility to skin, hair and nails. Collagen is an essential and major component of muscles, tendons, cartilage, ligaments, joints and blood vessels.

23. U.S. Patent #6,025,327 was filed on August 8, 1997 and issued on February 15, 2000. This patent protects Hydrolyzed Collagen Type II powder compositions, method of preparing the compositions and the use of the compositions in treating cartilage defects. This patent also protects the method of administering the compositions to an individual in need of cartilage augmentation in a daily dosage of between about 2,000 and 3,000 mg per day. (A true and correct copy of U.S. Patent #6,025,327 taken from the USPTO online database is attached hereto as "**Exhibit A**").

24. U.S. Patent #6,323,319 was filed on December 2, 1999 and issued on November 27, 2001. This patent protects Hydrolyzed Collagen Type II powder compositions, method of preparing the compositions and use of the compositions in treating cartilage defects. This patent also protects the method of administering the collagen to an individual in need of cartilage augmentation in a daily dosage of between about 2,000 and 3,000 mg per day. (A true and correct copy of U.S. Patent #6,323,319 taken from the USPTO online database is attached hereto as "**Exhibit B**").

25. U.S. Patent #6,838,440 was filed on January 24, 2001 and issued on January 4, 2005. This patent protects Kolla2 powder compositions, method of preparing the compositions and use of the compositions in treating arthritic joint cartilage disease. This patent also protects the method of administering the compositions to a human in need of cartilage cell repair in a daily dietary supplement dosage of between about 2,400 mg and 3,600 mg. (A true and correct copy of U.S. Patent #6,838,440 taken from the USPTO online database is attached hereto as "**Exhibit C**").

26. U.S. Patent #8,344,106 was filed on August 3, 2011 and issued on January 1, 2013. This patent protects a collagen mixture having a portion of unhydrolyzed eggshell membrane collagen and Avian collagen. (A true and correct copy of U.S. Patent #8,344,106 taken from the USPTO online database is attached hereto as "**Exhibit D**").

27. There are three main types of collagen: I, II and III. Types I and III are primarily found in skin, tendon and bone. In contrast, type II is found predominantly in articular cartilage.

28. Collagen Type II has many commercial uses, including use as a therapeutic agent and nutritional supplement for the treatment of cartilage defects and to promote the repair of damaged connective tissue.

29. After a quarter of a century of Collagen food supplement research, Certified Nutraceuticals created KollaGen II-XS™ (patented), a new unique avian Collagen Type II. Collagen Type II is the major component of joint cartilage and clinical studies have demonstrated that KollaGen II-XS™ significantly reduces joint pain and inflammation. KollaGen II-XS™ is the result of years of innovative research by Certified Nutraceuticals' R&D team.

30. Ahmad Alkayali, CEO of Certified Nutraceuticals, is listed as the assignee and inventor in connection with United States Patent No. 6,323,319, entitled "Method of making hydrolyzed collagen type II," which was issued on or about November 11, 2001. A copy of Patent No. 6,323,319 is attached hereto as "**Exhibit B**". Among other things, Patent No. 6,323,319 specifically claims "a method for preparing chicken sternal cartilage-derived material comprising hydrolyzed collagen type II powder."

31. Patent No. 6,323,319 is related to Patent No. 6,025,327. Patent No. 6,025,327 is entitled "Hydrolyzed collagen type II and use thereof," and was issued on or about February 15, 2000. A copy of Patent No. 6,025,327 is attached hereto as "**Exhibit A**". Like Patent No. 6,323,319, Patent No. 6,025,327 also lists Plaintiff as the inventor and claims a method of preparing hydrolyzed collagen type II using chicken sternal cartilage, among other things.

B. Defendants

32. Defendants, and each of them, are competitors that are infringing on Plaintiff's patents.

33. Defendant NUTRAWISE, INC. is, or has been, selling and labelling "Hydrolyzed Chicken Collagen Type II" in 600mg capsules and is producing, selling and labeling the same compound mixed with bovine collagen Type I&III in tablet form. This Defendant advertises and sells its infringing product through channels of commerce

including but not limited to a website known as "www.youtheory.com". Clinical research has not been conducted on said product even though NUTRAWISE, INC. is claiming medicinal benefits.

34. Defendant NUTRAWISE, INC.'s product is infringing on Plaintiff's U.S. Patent #8,344,106 B1; #6,323,319; #6,838,440; and #6,025,327 as further described above.

35. Defendant DARREN RUDE is the owner of NUTRWISE, INC. and has directly or through its intermediaries contributed to NUTRAWISE, INC.'s infringement of the stated patents by directing the sale, developing, licensing, manufacturing, shipping, distributing, offering for sale, selling, and advertising its product in the United States, the State of California and this district. DARREN RUDE has therefore purposefully and voluntarily placed said product into the stream of commerce with the expectation that it will be purchased in this district.

36. Defendant NEOCELL CORPORATION is, or has been, selling and labeling "Hydrolyzed Chicken Collagen Type II" in 600mg capsules and sold under the brand name "ImmuCell®". Clinical research has not been conducted on said product even though NEOCELL CORPORATION is claiming medicinal benefits.

37. Defendant NEOCELL CORPORATION's product is infringing on Plaintiff's U.S. Patent #8,344,106 B1; #6,323,319; #6,838,440; and #6,025,327as further described above. In addition, Defendant NEOCELL CORPRATION has made false statements concerning the contents of its infringing product "Rooster Comb" which contains fake Natural Hyaluronic Acid. (A true and correct copy of NEOCELL CORPORATION's online advertised infringing products attached hereto as "**Exhibit E**").

38. Defendant COLLAGEN M.D., INC. is, or has been, selling and labeling "Hydrolyzed Chicken Collagen Type II" in capsule form mixed with pomegranate derived ingredients. Clinical research has not been conducted on said product even though COLLAGEN M.D., INC. is claiming medicinal benefits.

39. Defendant COLLAGEN M.D., INC.'s product is infringing on Plaintiff's U.S. Patent #8,344,106 B1; #6,323,319; #6,838,440; and #6,025,327as further described above.

40. Defendant AXE WELLNESS is, or has been, selling, labeling and promoting "Hydrolyzed Chicken Collagen Type II" in capsule form with chicken egg membrane. Defendant AXE WELLNESS is further mixing collagen Type I, II, III, V and X. Clinical research has not been conducted on said product even though AXE WELLNESS is claiming medicinal benefits.

41. Defendant AXE WELLNESS's product is infringing on Plaintiff's U.S. Patent #8,344,106 B1; #6,323,319; #6,838,440; and #6,025,327 as further described above.

42. Defendant DR. VENESSA'S FORMULAS is, or has been, selling, labeling and promoting "Hydrolyzed Chicken Collagen Type II" in capsules mixed with bovine collagen Type I&III in tablet form. Clinical research has not been conducted on said product even though DR. VENESSA'S FORMULAS is claiming medicinal benefits.

43. Defendant DR. VENESSA'S FORMULAS's product is infringing on Plaintiff's U.S. Patent #8,344,106 B1; #6,323,319; #6,838,440; and #6,025,327 as further described above.

44. Defendant IRIS TRADING is, or has been, selling, labeling and promoting "Hydrolyzed Chicken Collagen Type II" derived from chicken sternum and manufactured in capsule form. Plaintiff is informed, believes and thereon alleges that IRIS TRADING purchases ingredients for said product from China distributors. Clinical research has not been conducted on said product even though IRIS TRADING is claiming medicinal benefits.

45. Defendant IRIS TRADING's product is infringing on Plaintiff's U.S. Patent #8,344,106 B1; #6,323,319; #6,838,440; and #6,025,327 as further described above.

46. Defendant NUTRA FOOD INGREDIENTS is, or has been, selling, labeling and promoting "Hydrolyzed Chicken Collagen Type II" derived from fresh chicken

cartilage and manufactured in 20 kilogram powder drum. Plaintiff is informed, believes and thereon alleges that NUTRA FOOD INGREDIENTS purchases ingredients for said product from China distributors. Clinical research has not been conducted on said product even though NUTRA FOOD INGREDIENTS is claiming medicinal benefits.

47. Defendant NUTRA FOOD INGREDIENTS' product is infringing on Plaintiff's U.S. Patent #8,344,106 B1; #6,323,319; #6,838,440; and #6,025,327 as further described above.

48. Defendant MERCOLA.COM HEALTH RESOURCES, LLC is, or has been, selling, labeling and promoting "Hydrolyzed Chicken Collagen Type II" derived from chicken cartilage and Eggshell Membrane which are manufactured in 100 milligram tablets and administered as a pet joint formula.

49. Defendant MERCOLA.COM HEALTH RESOURCES, LLC's product is infringing on Plaintiff's U.S. Patent #8,344,106 B1; #6,323,319; #6,838,440; and #6,025,327 as further described above.

50. Defendant DR. JOSEPH MERCOLA is believed to be the owner of MERCOLA.COM HEALTH RESOURCES, LLC and has directly or through its intermediaries contributed to MERCOLA.COM HEALTH RESOURCES, LLC's infringement of the stated patents by directing the sale, developing, licensing, manufacturing, shipping, distributing, offering for sale, selling, and advertising its product in the United States, the State of California and this district. DR. JOSEPH MERCOLA has therefore purposefully and voluntarily placed said product into the stream of commerce with the expectation that it will be purchased in this district.

51. Defendant VESTA INGREDEINTS, INC. is, or has been, selling, labeling and promoting "Hydrolyzed Chicken Collagen Type II" and collagen type I&III and are distributed in 1 to 25 kilogram packages. Clinical research has not been conducted on said product even though VESTA INGREDIANTS, INC. is claiming medicinal benefits. Specifically, this Defendant has published a flyer stating the use of collagen types I, II&III in its products as well as the intended medicinal benefits of the product. (A true

and correct copy of VESTA INGREDIENTS, INC.'s flyer attached hereto as "**Exhibit F**".

52. Defendant VESTA INGREDIENTS, INC.'s product is infringing on Plaintiff's U.S. Patent #8,344,106 B1; #6,323,319; #6,838,440; and #6,025,327 as further described above.

53. Defendant NUTRACEUTICAL CORPORATION, is, or has been, selling, labeling and promoting "Hydrolyzed Chicken Collagen Type II" distributed in 1,000 milligram, 60 tablet bottles mixed with Chondroitin and proteins advertised for individual use to promote joint health. Clinical research has not been conducted on said product even though NURTRACEUTICAL CORPORATION is claiming medicinal benefits. Specifically, this Defendant manufacturers, or contributes in the manufacturing of, a product known as "Clinical Youth Collagen". (Two images of NUTRACEUTICAL CORPORATION's infringing product are attached hereto as "**Exhibit G**").

54. Defendant NUTRACEUTICAL CORPORATION's product is infringing on Plaintiff's U.S. Patent #8,344,106 B1; #6,323,319; #6,838,440; and #6,025,327 as further described above.

55. Defendant NEW ENGLAND GREENS, LLC., is, or has been, selling, labeling and promoting "Hydrolyzed Chicken Collagen Type II" and collagen Type I distributed in powder supplement form advertised for individual use to promote joint health. Specifically, this Defendant manufacturers, or contributes in the manufacturing of, a product known as "Joint Vibrance". (A true and correct copy of NEW ENGLAND GREENS, LLC's advertisement flyer for "Joint Vibrance" is attached hereto as "**Exhibit H**").

56. Defendant NEW ENGLAND GREENS, LLC's product is infringing on Plaintiff's U.S. Patent #8,344,106 B1; #6,323,319; #6,838,440; and #6,025,327 as further described above.

57. Defendants, and each of them, are knowingly, purposefully and voluntarily infringing on Plaintiff's protected rights under the patents in suit.

FIRST CAUSE OF ACTION: PATENT INFRINGEMENT

(As Against All Defendants)

58. Plaintiff repeats and re-allege the allegations of the foregoing paragraphs of this Complaint as if fully set forth herein.

59. Defendants have in the past and still are literally infringing or infringing under the doctrine of equivalents one or more claims of the patents in suit by making, using, selling, and offering for sale the accused products, and will continue to do so unless enjoined by this Court.

60. End-users of Defendants' accused products are direct infringers of one or more claims of the patents in suit.

61. End-users of Defendants' accused products have taken, used, and orally administered the accused products.

62. The accused products are formulated, made, manufactured, shipped, distributed, advertised, offered for sale, and sold by Defendants to include Collagen that, by virtue of its inclusion in the products, infringe one or more claims of the patents in suit.

63. The accused products are formulated, made, manufactured, shipped, distributed, advertised, offered for sale, and sold by Defendants to include Collagen for purposes that, by their inclusion in the products for such purposes, infringe one or more claims of the patents in suit, and as a result, when end-users of Defendants' accused products orally administer the accused products, they are practicing the methods disclosed in one or more claims of that patent.

64. Defendants' labels and advertising for the accused products explain the elements and essential elements of the methods disclosed in the patents in suit, and those labels and advertising statements encourage, urge, and induce the accused products' end-users to purchase and orally ingest the products to practice those methods, and end-users do practice those methods.

65. Defendants have therefore specifically intended to cause these end-users to directly infringe the claimed methods of the patents in suit, and have in fact urged them to do so.

66. The accused products are not suitable for non-infringing uses, and none of Defendants' labels or advertisements for the accused products disclose any uses for the products, nor for the compounds disclosed in the claimed methods, that do not infringe upon such methods.

67. The inclusion of these specific infringing ingredients in the products is material to practicing such methods.

68. Defendants have knowledge that the accused products are especially adapted by end-users of the products for the practicing of such methods, and, indeed, Defendants encourage, urge, and induce the accused products' end-users to purchase and orally administer the accused products to practice such methods, and have done so in the past.

69. Defendants have intentionally and knowingly induced, encouraged, and urged end-users of the accused products to purchase and orally administer the accused products for the purposes disclosed in one or more claims of the patents in suit by having them orally ingest the compounds disclosed in such claims.

70. Defendants have knowledge of the fact that the accused products, particularly as administered, infringe on one or more claims of the patents in suit.

71. Defendants also have direct, firsthand knowledge of the patents in suit.

72. Defendants' activities have been without express or implied license by Plaintiff.

73. As a result of Defendants' acts of infringement, Plaintiff has suffered and will continue to suffer damages in an amount to be proved at trial.

74. As a result of Defendants' acts of infringement, Plaintiff has been and will continue to be irreparably harmed by Defendants' infringements, which will continue unless Defendants are enjoined by this Court.

75. The "application" for the patents in suit and claims therein are substantially identical to the "issued" patents in suit and claims therein, warranting pre-patent issuance damages in favor of Plaintiff.

76. Defendants' past infringements and/or continuing infringements have been deliberate and willful, and this case is therefore an exceptional case, which warrants an award of treble damages and attorneys' fees in accordance with 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for entry of judgment against Defendants as follows:

77. A declaration that Defendants have infringed the patent in suit, under 35 U.S.C. §§ 271 *et seq.*;

78. That preliminary and permanent injunctions be issued restraining Defendants, its officers, agents, servants, directors, and employees, and all persons in active concert or participation with each, from directly or indirectly infringing, or inducing or contributing to the infringement by others of, the patent in suit;

79. That Defendants be required to provide to Plaintiff an accounting of all gains, profits, and advantages derived by Defendants' infringement of the patent in suit, and that Plaintiff be awarded damages adequate to compensate Plaintiff for the wrongful infringing acts by Defendants, in accordance with 35 U.S.C. § 284;

80. That the damages awarded to Plaintiff, with regard to the patents in suit, be increased up to three times, in view of Defendants' willful infringement, in accordance with 35 U.S.C. § 284;

81. That this case be declared to be exceptional in favor of Plaintiff under 35 U.S.C. § 285, and that Plaintiff be awarded its reasonable attorneys' fees and other expenses incurred in connection with this action;

82. That Plaintiff be awarded its interest and costs of suit incurred in this action;

83. That Plaintiff be awarded compensatory damages;

84. That Plaintiff be awarded pre-patent issuance damages;

85. That Plaintiff be awarded punitive damages; and

86. That Plaintiff be awarded such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury.

DATED: July 11, 2017

Respectfully Submitted,

KHASHYAR LAW GROUP

Daryoosh Khashayar, Esq.
Attorneys for Plaintiff,
CERTIFIED NUTRACEUTICALS, INC.

Exhibit “A”

USPTO PATENT FULL-TEXT AND IMAGE DATABASE

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Images

United States Patent **6,025,327**
Alkayali **February 15, 2000**

Hydrolyzed collagen type II and use thereof

Abstract

Hydrolyzed collagen type II powder compositions, method of preparing the compositions and use of the compositions in treating cartilage defects. The compositions are orally administered to an individual in need of cartilage augmentation in a daily dosage of between about 2,000 and 3,000 mg per day.

Inventors: **Alkayali; Ahmed** (Laguna Beach, CA)
Assignee: **Biocell Technology, LLC** (Newport Beach, CA)
Family ID: **25424560**
Appl. No.: **08/907,735**
Filed: **August 8, 1997**

Current U.S. Class:	**514/17.2**; 435/212; 435/273; 530/356
Current CPC Class:	C07K 14/78 (20130101); A61K 38/00 (20130101)
Current International Class:	C07K 14/435 (20060101); C07K 14/78 (20060101); A61K 38/12 (20060101); A61K 038/39 (); C07K 014/78 ()
Field of Search:	;530/356,412 ;514/2 ;435/212,273

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5399347	March 1995	Trentham et al.
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Foreign Patent Documents

WO 97/254435 Jul 1997 WO

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Primary Examiner: Woodward; Michael P.
Assistant Examiner: Gupta; Anish
Attorney, Agent or Firm: Knobbe, Martens, Olson & Bear, LLP

Claims

What is claimed is:

1. Chicken sternal cartilage-derived material comprising hydrolyzed collagen type II, said hydrolyzed collagen type II having an average molecular weight of between about 1,500 and 2,500 daltons.

2. A method for treating an individual with a connective tissue disorder, comprising orally administering to said individual an effective daily amount of chicken sternal cailage-derived material comprising hydrolyzed collagen type II having an average molecular weight of between about 1,500 and 2,500 daltons.

3. The method of claim 2, wherein said connective tissue disorder is selected from the group consisting of degenerative joint diseases, joint defects, osteoarthritis, polychondritis, vascular disease, cartilage injuries, progressive myopia and Menier's disease.

4. A method for treating an individual with a connective tissue disorder, comprising orally administering to said individual an effective daily amount of chicken sternal cartilage-derived material comprising hydrolyzed collagen type II, wherein said effective daily amount is between about 500 and 5,000 mg.

5. The method of claim 4, wherein said effective daily amount is between about 2,000 and 4,000 mg.

6. The method of claim 5, wherein said effective daily amount is between about 2,000 and 3,000 mg.

7. A method of providing collagen type II as a nutritional supplement, comprising orally administering to an individual a daily dosage of chicken sternal cartilage-derived material comprising hydrolyzed collagen type II having an average molecular weight of between about 1,500 and 2,500 daltons.

Description

FIELD OF THE INVENTION

The present invention relates to a method of preparing hydrolyzed collagen type II and its use as a therapeutic agent and nutritional supplement.

BACKGROUND OF THE INVENTION

Collagen is a complex structural protein which provides strength and flexibility to skin, hair and nails. Collagen is an essential and major component of muscles, tendons, cartilage, ligaments, joints and blood vessels. There are three main types of collagen: I, II and III. Types I and III are primarily found in skin, tendon and bone. In contrast, type II is found predominantly in articular cartilage. Collagen is an unusual protein, in that the proportion of glycine residues is nearly one-third which is unusually high. Proline is also present to a much greater extent in collagen than in most other proteins. Moreover, collagen contains two amino acids, 4-hydroxyproline and 5-hydroxylysine, that are found in very few other proteins. The amino acid sequence of collagen is remarkably regular, nearly every third amino acid being glycine. In addition, the sequence glycine-proline-hydroxyproline recurs frequently. In contrast, globular proteins rarely exhibit regularities in their amino acid sequences (Stryer, L., Biochemistry, Third Edition, W. H. Freeman and Co., New York, 1988, pp. 262).

In 1986, collagen was sold for the first time in the United States for use as a food supplement. Collagen (a mixture of Types I and II) was extracted from calf skin tissue, hydrolyzed and prepared in powdered form for use as a dietary supplement. The composition was sold under the name "Hydrolyzed Collagen Beauty Supplement.TM." (Smarter Nails & Hair, Inc., Newport Beach, Calif.). In 1987, "Hydrolyzed Collagen Beauty Supplement Tablet.TM." (Smarter Nails & Hair, Inc., Newport Beach, Calif.) was sold which comprised collagen powder and 10 mg vitamin C compressed into 1,000 mg tablets.

U.S. Pat. No. 4,804,745 to Koepff et al. discloses agents containing collagen peptides produced by enzymatic hydrolysis for the treatment of degenerative joint diseases. These peptides can be obtained from animal skin, animal bones and other sufficiently purified connective tissue and have average molecular weights of between 30 and 45 kilodaltons.

U.S. Pat. No. 5,399,347 to Trentham et al. and Trentham et al. (Science 261:1727-1729, 1993) disclose the effective treatment of rheumatoid arthritis (RA) with water-soluble whole chick collagen type II or biologically active peptides derived therefrom. The mechanism by which the effect is believed to occur is via oral tolerization to autoantigens.

U.S. Pat. No. 5,364,845 to Henderson discloses a therapeutic composition and method for the protection, treatment and repair of connective tissue in mammals. This composition comprises glucosamine, chondroitin

sulfate and manganese ascorbate. U.S. Pat. No. 5,587,363 to Henderson discloses a therapeutic composition and method for the protection, treatment and repair of connective tissue in mammals which includes aminosugars and glycosaminoglycans.

There is a constant need for compositions capable of promoting repair of damaged connective tissue. The present invention addresses this need.

SUMMARY OF THE INVENTION

One embodiment of the present invention is hydrolyzed collagen type II, the hydrolyzed collagen having an average molecular weight of between about 1,500 and 2,500 daltons. Preferably, the hydrolyzed collagen type II has an average molecular weight of about 1,800 daltons. In one aspect of this preferred embodiment, the collagen is obtained from chicken sternal cartilage.

The present invention also provides a method of inducing cartilage formation in an individual with a connective tissue disorder, comprising orally administering to the individual an effective daily cartilage-inducing amount of hydrolyzed collagen type II. The connective tissue disorder includes degenerative joint diseases, joint defects, osteoarthritis, polychondritis, vascular disease and cartilage injuries. Preferably, the effective daily amount is between about 500 and 5,000 mg. More preferably, the effective daily amount is between about 1,000 and 4,000 mg. Most preferably, the effective daily amount is between about 2,000 and 3,000 mg.

Another embodiment of the invention is a method of providing collagen type II as a nutritional supplement, comprising orally administering to an individual a daily dosage of hydrolyzed collagen having an average molecular weight of between about 1,500 and 2,500 daltons.

Still another embodiment of the invention is a method of preparing hydrolyzed collagen type II powder, comprising the following steps: cutting fresh chicken sternal cartilage to within not less than about 2 mm of the bone; suspending the cartilage in an aqueous solution; treating said cartilage with a proteolytic enzyme to form a hydrolysate; sterilizing the hydrolysate; filtering the hydrolysate; concentrating the hydrolysate; and drying the hydrolysate to form a collagen type II powder. The method may further comprise the step of freezing the cartilage after the cutting step. Preferably, the aqueous solution is water. Advantageously, the enzyme is papain, ficin or bromelain. In one aspect of this preferred embodiment, the sterilizing step comprises heating the hydrolysate at 95.degree. C. for about 30 minutes. Preferably, the drying step comprises spray drying. Preferably, the pH of the suspending and treating steps is between about 4 and 8.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of the process for preparing the hydrolyzed collagen type II powder of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a hydrolyzed, denatured collagen type II composition, method for preparing the composition and use of the composition in the prevention, treatment and repair of cartilage defects. The method involves cutting fresh sternal cartilage from chicken carcasses and removing all meat therefrom. The sternal cartilage is cut, leaving a space of about two millimeters from the bone so as to not remove any bone fragments. This is critical to the purity of the final product because it avoids contamination of collagen type II with types I and III found in bone. The fresh sternal cartilage is then promptly frozen and the remainder of the chicken carcass is discarded. It is exclusively the sternal cartilage, cut so no bone is included, that is used for preparing the collagen type II powder. The chicken sternal cartilage is processed according to good manufacturing procedures (GMP). Other contemplated sources of collagen type II are mammalian cartilage (i.e. bovine and porcine) and shark fins.

The production of hydrolyzed collagen type II in powdered form is shown in FIG. 1. Whole cartilage is

suspended in an aqueous solution, preferably water, for about one hour at about 35.degree. C. at a pH of between about 4 and 8. In a preferred embodiment, the pH is between about 6 and 7. In a more preferred embodiment, the pH is about 6.5. The water is removed, and the cartilage is incubated with one or more proteases obtainable from a natural source (i.e. papain, ficin, bromelain) for between about 2 and 10 hours, preferably about 6 hours, at about 35.degree. C.-55.degree. C. at a pH of between about 4 and 8 to form a hydrolysate. The pH will depend on the pH optimum of the particular enzyme(s) used for the hydrolysis and are well known to one of ordinary skill in the art. The hydrolysate is then sterilized for about 30 minutes at a temperature between about 95.degree. C. and 105.degree. C. The sterilized hydrolysate is filtered through diatomaceous earth, concentrated, preferably under vacuum, dried to form a powder and packed. Other filtration methods are contemplated, including vacuum filtration. In a preferred embodiment, the hydrolyzed collagen type II is spray dried using a size 56 pressure nozzle into a heat tunnel. The final particle size and mesh are adjusted to 0.46 g/cc, yielding a fine powder. The powder is packed in a 40 kg drum with a plastic bag liner. The powder is water soluble.

The average molecular weight of the final product is between 1,500 and 2,500 daltons, preferably 1,800 daltons. The moisture content is between 5% and 7%. The final product is high in mucopolysaccharides, particularly chondroitin sulfate and glucosamine sulfate. The product has 375 calories per 100 grams, contains 67% protein (12.1% total nitrogen), 18% carbohydrate and 0.1% fat. The amino acid composition of the hydrolysate differs substantially from typical collagens and is shown in Table 1. Hydroxyproline is low, hydroxylysine is absent and tryptophan is low. The molecular weight and amino acid composition promote optimal assimilation of the peptides.

TABLE 1 _____ Amino acid composition of hydrolyzed collagen type II Amino acid g/100 g product _____ arginine 4.42 histidine 2.05 isoleucine 1.90 leucine 4.20 lysine 3.54 methionine 1.38 phenylalanine 2.14 threonine 2.60 tryptophan 0.37 alanine 4.51 asparagine/aspartic acid 5.29 cystine 0.46 glutamine/glutamic acid 8.75 glycine 8.93 hydroxyproline 3.90 proline 5.25 serine 2.45 tyrosine 1.16 valine 2.43

_____

When taken orally by an individual with a connective tissue disorder, hydrolyzed collage type II helps build cartilage and significantly improves the disorder. "Oral" administration includes oral, enteral or intragastric administration. The hydrolyzed collagen type II of the invention can be used to treat, for example, degenerative joint diseases (i.e. rheumatoid arthritis), joint defects, osteoarthritis, polychondritis, vascular disease, cartilage injuries, silicone poisoning due to ruptured breast implants, autoimmune diseases involving connective tissue autoantibodies (i.e. rheumatoid arthritis), progressive myopia, Menier's disease and any other connective tissue disorder which would benefit from increased synthesis of cartilage. The hydrolyzed collagen type II also significantly reduces sun-induced skin wrinkles.

For oral administration as a nutritional supplement, therapeutic or prophylactic agent, the hydrolyzed collagen type II of the invention may be provided as a dispersible powder or granule, tablet, aqueous or oil suspension, emulsion, hard or soft capsule, syrup or elixir. Compositions intended for oral use may be prepared according to any method known in the art for the manufacture of pharmaceutical compositions and such compositions may contain one or more of the following agents: sweeteners, flavoring agents, coloring agents and preservatives. The sweetening and flavoring agents will increase the palatability of the preparation. Tablets containing the hydrolyzed collagen type II in admixture with non-toxic pharmaceutically acceptable excipients suitable for tablet manufacture are acceptable. Such excipients include inert diluents such as calcium carbonate, sodium carbonate, lactose, calcium phosphate or sodium phosphate; granulating and disintegrating agents, such as corn starch or alginic acid; binding agents such as starch, gelatin or acacia; and lubricating agents such as magnesium stearate, stearic acid or talc. Tablets may be uncoated or may be coated by known techniques to delay disintegration and absorption in the gastrointestinal tract and thereby provide a sustained action over a longer period of time. For example, a time delay material such as glyceryl monostearate or glyceryl distearate alone or with a wax may be employed. The use of enteric coatings is also contemplated.

Formulations for oral use may also be presented as hard gelatin capsules wherein the active ingredient is mixed with an inert solid diluent, for example calcium carbonate, calcium phosphate or kaolin, or as soft gelatin

capsules wherein the active ingredient is mixed with water or an oil medium, such as peanut oil, liquid paraffin or olive oil.

Aqueous suspensions may contain the hydrolyzed collagen type II of the invention in admixture with excipients suitable for the manufacture of aqueous suspensions. Such excipients include suspending agents, dispersing or wetting agents, one or more preservatives, one or more coloring agents, one or more flavoring agents and one or more sweetening agents such as sucrose or saccharin.

Oil suspensions may be formulated by suspending the active ingredient in a vegetable oil, such as arachis oil, olive oil, sesame oil or coconut oil, or in a mineral oil such as liquid paraffin. The oil suspension may contain a thickening agent, such as beeswax, hard paraffin or cetyl alcohol. Sweetening agents, such as those set forth above, and flavoring agents may be added to provide a palatable oral preparation. These compositions may be preserved by an added antioxidant such as ascorbic acid. Dispersible powders and granules of the invention suitable for preparation of an aqueous suspension by the addition of water provide the active ingredient in admixture with a dispersing or wetting agent, a suspending agent, and one or more preservatives. Additional excipients, for example sweetening, flavoring and coloring agents, may also be present.

Syrups and elixirs may be formulated with sweetening agents, such as glycerol, sorbitol or sucrose. Such formulations may also contain a demulcent, a preservative, a flavoring agent and/or a coloring agent.

The hydrolyzed collagen type II powder may be mixed with other ingestible forms and consumed in solid, semi-solid solution, suspension or emulsion form. It may also be mixed in conjunction or alternatively with pharmaceutically acceptable carriers, flavor enhancers, water, suspending agents and emulsifying agents. In a preferred embodiment, the hydrolyzed collagen type II powder is mixed with a citrus juice such as orange, grapefruit or tangerine due to the promotion of connective tissue formation by ascorbic acid. The hydrolyzed collagen may also be provided in tablet form in admixture with ascorbic acid.

For use as a nutritional supplement, prophylactic or therapeutic agent, the hydrolyzed collagen is orally administered in a daily dosage of between about 500 mg and 5,000 mg. More preferably, it is administered in a daily dosage of between about 2,000 mg and 4,000 mg. Most preferably, it is administered in a daily dosage of between about 2,000 and 3,000 mg per day. The hydrolyzed collagen type II powder may be formulated into tablets which range from 300 mg to 1,000 mg per tablet. In a preferred embodiment, the hydrolyzed collagen type II powder is formulated into 500 mg tablets and 4-6 tablets are taken daily. In another preferred embodiment, the tablets are taken on an empty stomach with a beverage containing vitamin C.

In another preferred embodiment, the hydrolyzed collagen type II powder is mixed with water or a citrus juice prior to ingestion. The preparations described above can be taken indefinitely by individuals affected by connective tissue disorders or by healthy individuals as a preventative agent. If desired, an individual with such a disorder can take the preparation until no further improvement is noted in the disorder.

The above detailed description of the invention is set forth solely to assist in understanding the invention. It is to be understood that variations of the invention, including all equivalents now known or later developed, are to be considered as falling within the scope of the invention, which is limited only by the following claims.

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United States Patent **6,323,319**
Alkayali **November 27, 2001**

Method of making hydrolyzed collagen type II

Abstract

Hydrolyzed collagen type II powder compositions, method of preparing the compositions and use of the compositions in treating cartilage defects. The compositions are orally administered to an individual in need of cartilage augmentation in a daily dosage of between about 2,000 and 3,000 mg per day.

Inventors: **Alkayali; Ahmed** (Laguna Beach, CA)
Assignee: **Five Continent Enterprise, Inc.** (Newport Beach, CA)
Family ID: **25424560**
Appl. No.: **09/453,302**
Filed: **December 2, 1999**

Related U.S. Patent Documents

Application Number	Filing Date	Patent Number	Issue Date
907735	Aug 8, 1997	6025327	

Current U.S. Class: **530/356**; 435/212; 435/273; 530/407; 530/412
Current CPC Class: C07K 14/78 (20130101); A61K 38/00 (20130101)
Current International Class: C07K 14/435 (20060101); C07K 14/78 (20060101); A61K 38/12 (20060101); C07K 001/12 (); C07K 014/78 ()
Field of Search: ;530/344,356,407,412 ;435/212,273 ;514/2

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Assistant Examiner: Gupta; Anish
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Parent Case Text

This application is a continuation of U.S. patent application Ser. No. 08/907,735, filed Aug. 8, 1997, now U.S. Pat. No. 6,025,327.

Claims

What is claim is:

1. A method for preparing chicken sternal cartilage-derived material comprising hydrolyzed collagen type II

powder, comprising the following steps:

(a) cutting fresh chicken sternal cartilage to within not less than about 2 mm of the bone;

(b) suspending said cartilage in an aqueous solution;

(c) treating said cartilage with a proteolytic enzyme to form a hydrolysate, said proteolytic enzyme being capable of hydrolyzing collagen type II to fragments having an average molecular weight of between 1,500 and 2,500 daltons;

(d) sterilizing said hydrolysate;

(e) filtering said hydrolysate;

(f) concentrating said hydrolysate;

(g) drying said hydrolysate to form a powder enriched in collagen type II; and

(h) isolating said powder enriched in collagen type II.

2. The method of claim 1, further comprising the step of freezing said cartilage after said cutting step.

3. The method of claim 1, wherein said aqueous solution is water.

4. The method of claim 1, wherein said enzyme is selected from the group consisting of papain, ficin and bromelain.

5. The method of claim 1, wherein said sterilizing step comprises heating said hydrolysate at about 95.degree. C.-105.degree. C. for about 30 minutes.

6. The method of claim 1, wherein said drying step comprises spray drying.

7. The method of claim 1, wherein step (b) is performed at a pH between 4 and 8.

8. The method of claim 1, wherein step (c) is performed at a pH between 4 and 8.

Description

FIELD OF THE INVENTION

The present invention relates to a method of preparing hydrolyzed collagen type II and its use as a therapeutic agent and nutritional supplement.

BACKGROUND OF THE INVENTION

Collagen is a complex structural protein which provides strength and flexibility to skin, hair and nails. Collagen is an essential and major component of muscles, tendons, cartilage, ligaments, joints and blood vessels. There are three main types of collagen: I, II and III. Types I and III are primarily found in skin, tendon and bone. In contrast, type II is found predominantly in particular cartilage. Collagen is an unusual protein, in that the proportion of glycine residues is nearly one-third which is unusually high. Proline is also present to a much greater extent in collagen than in most other proteins. Moreover, collagen contains two amino acids, 4-hydroxyproline and 5-hydroxylysine, that are found in very few other proteins. The amnino acid sequence of

collagen is remarkably regular, nearly every third amino acid being glycine. In addition, the sequence glycine-proline-hydroxyproline recurs frequently. In contrast, globular proteins rarely exhibit regularities in their amino acid sequences (Stryer, L., Biochemistry, Third Edition, W. H. Freeman and Co., New York, 1.988, pp. 262).

In 1986, collagen was sold for the first time in the United States for use as a food supplement Collagen (a mixture of Types I, II) was extracted from calf skin tissue, hydrolyzed and prepared in powdered form for use as a dietary supplement. The composition was sold under the name "Hydrolyzed Collagen Beauty Supplement.TM." (Smarter Nails & Hair, Inc., Newport Beach, Calif.). In 1987, "Hydrolyzed, Collagen Beauty Supplement Tablet.TM." (Smarter Nails & Hair, Inc., Newport Beach, Calif.) was sold which comprised collagen powder and 10 mg vitamin C compressed into 1,000 mg tablets.

U.S. Pat. No. 4,804,745 to Koepff et al. discloses agents containing collagen peptides produced by enzymatic hydrolysis for the treatment of degenerative joint diseases. These peptides can be obtained from animal skin, animal bones and other sufficiently purified connective tissue and have average molecular weights of between 30 and 45 kilodaltons.

U.S. Pat. No. 5,399,347 to Trentham et al. and Trentham et al. (Science 261:1727-1729, 1993) disclose the effective treatment of rheumatoid arthritis (RA) with water-soluble whole chick collagen type II or biologically active peptides derived therefrom. The mechanism by which the effect is believed to occur is via oral tolerization to autoantigens.

U.S. Pat. No. 5,364,845 to Henderson discloses a therapeutic composition and method for the protection, treatment and repair of connective tissue in mammals. This composition comprises glucosamine, chondroitin sulfate and manganese ascorbate. U.S. Pat. No. 5,587,363 to Henderson discloses a therapeutic composition and method for the protection, treatment and repair of connective tissue in mammals which includes aminosugars and glycosaminoglycans.

There is a constant need for compositions capable of promoting repair of damaged connective tissue. The present invention addresses this need.

SUMMARY OF THE INVENTION

One embodiment of the present invention is hydrolyzed collagen type II, the hydrolyzed collagen having an average molecular weight of between about 1,500 and 2,500 daltons. Preferably, the hydrolyzed collagen type II has an average molecular weight of about 1,800 daltons. In one aspect of this preferred embodiment, the collagen is obtained from chicken sternal cartilage.

The present invention also provides a method of inducing cartilage formation in an individual with a connective tissue disorder, comprising orally administering to the individual an effective daily cartilage-inducing amount of hydrolyzed collagen type II. The connective tissue disorder includes degenerative joint diseases, joint defects, osteoarthritis, polychondritis, vascular disease and cartilage injuries. Preferably, the effective daily amount is between about 500 and 5,000 mg. More preferably, the effective daily amount is between about 1,000 and 4,000 mg. Most preferably, the effective daily amount is between about 2,000 and 3,000 mg.

Another embodiment of the invention is a method of providing collagen type II as a nutritional supplement, comprising orally administering to an individual a daily dosage of hydrolyzed collagen having an average mole weight of between about 1,500 and 2,500 daltons.

Still another embodiment of the invention is a method of preparing hydrolyzed collagen type II powder, comprising the following steps: cutting fresh chicken sternal cartilage to within not less than about 2 mm of the bone; suspending tho cartilage in an aqueous solution; treating said cartilage with a proteolytic enzyme to form a hydrolysate; sterilizing the hydrolysate; filtering the hydrolysate; concentrating the hydrolysate; and drying the hydrolysate to form a collagen type II powder. The method may further comprise the step of freezing the cartilage after the cutting step. Preferably, the aqueous solution is water. Advantageously, the enzyme is papain,

ficin or bromelain. In one aspect of this preferred embodiment, the sterilizing step comprises heating the hydrolysate at 95.degree. C. for about 30 minutes. Preferably, the drying step comprises spray drying. Preferably, the pH of the suspending and treating steps is between about 4 and 8.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of the process for preparing the hydrolyzed collagen type II powder of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a hydrolyzed, denatured collagen type II composition, method for preparing the composition and use of the composition in the prevention, treatment and repair of cartilage defects. The method involves cutting fresh sternal cartilage from chicken carcasses and removing all meat therefrom. The sternal cartilage is cut, leaving a space of about two millimeters from the bone so as to not remove any bone fragments. This is critical to the purity of the fmal product because it avoids contamination of collagen type II with types I and III found in bone. The fresh sternal cartilage is then promptly frozen and the remained of the chicken carcass is discarded. It is exclusively the sternal cartilage, cut so no bone is included, that is used for preparing the collagen type II powder. The chicken sternal cartilage is processed according to good manufacturing procedures (GMP). Other contemplated sources of collagen type II are mammalian curfilage (i.e. bovine and porcine) and shark fins.

The production of hydrolyzed collagen type II in powdered form is shown in FIG. 1. Whole cartilage is suspended in an aqueous solution, preferably water for about one hour at about 35.degree. C. at a pH of between about 4 and 8. In a preferred embodiment, the pH is between about 6 and 7. In a more preferred embodiment, the pH is about 6.5. The water is removed, and the cartilage is incubated with one or more proteases obtainable from a natural source (i.e. papain, ficin, bromelain) for between about 2 and 10 hours, preferably about 6 hours, at about 35.degree. C.-55.degree. C. at a pH of between about 4 and 8 to form a hydrolysate. The pH will depend on the pH optimum of the particular enzyme(s) used for the hydrolysis and are well known to one of ordinary skill in the art. The hydrolysate is then sterilized for about 30 minutes at a temperature between about 95.degree. C. and 105.degree. C. The sterilized hydrolysate is filtered through diatomaceous earth, concentrated, preferably under vacuum, dried to form a powder and packed. Other filtration methods are contemplated, including vacuum filtration. In a preferred embodiment, the hydrolyzed collagen type II is spray dried using a size 56 pressure nozzle into a heat tunnel. The final particle size and mesh are adjusted to 0.46 g/cc, yielding a fine powder. The powder is packed in a 40 kg drum with a plastic bag liner. The powder is water soluble.

The average molecular weight of the final product is between 1,500 and 2,500 daltons, preferably 1,800 daltons. The moisture content is between 5% and 7%. The final product is high in mucopolysaccharides, particularly chondroitin sulfate and glucosamine sulfate. The product has 375 calories per 100 grams, contains 67% protein (12.1% total nitrogen), 18% carbohydrate and 0.1% fat. The amino acid composition of the hydrolysate differs substantially from typical collagens and is shown in Table 1. Hydroxyproline is low, hydroxylysine is absent and tryptophan is low. The molecular weight and amino acid composition promote optimal assimilation of the peptides.

TABLE 1 Amino acid composition of hydrolyzed collagen type II Amino acid g/100 g product arginine 4.42 histidine 2.05 isoleucine 1.90 leucine 4.20 lysine 3.54 methionine 1.38 phenylalanine 2.14 threonine 2.60 tryptophan 0.37 alanine 4.51 asparagine/aspartic acid 5.29 cystine 0.46 glutamine/glutamic acid 8.75 glycine 8.93 hydroxyproline 3.90 proline 5.25 serine 2.45 tyrosine 1.16 valine 2.43

When taken orally by an individual with a connective tissue disorder, hydrolyzed collage type II helps build cartilage and significantly improves the disorder. "Oral" administration includes oral, enteral or intragastric administration. The hydrolyzed collagen type II of the invention can be used to treat, for example, degenerative joint diseases (i.e. rheumatoid arthritis), joint defects, osteoarthritis, polychondritis, vascular disease, cartilage injuries, silicone poisoning due to ruptured breast implants, autoimmune diseases involving connective tissue

autoantibodies (i.e. rheumatoid arthritis), progressive myopia, Menier's disease and any other connective tissue disorder which would benefit from increased synthesis of cartilage. The hydrolyzed collagen type II also significantly reduces sun-induced skin wrinkles.

For oral administration as a nutritional supplement, therapeutic or prophylactic agent, the hydrolyzed collagen type II of the invention may be provided as a dispersible powder or granule, tablet, aqueous or oil suspension, emulsion, hard or soft capsule, syrup or elixir. Compositions intended for oral use may be prepared according to any method known in the art for the manufacture of pharmaceutical compositions and such compositions may contain one or more of the following agents: sweeteners, flavoring agents, coloring agents and preservatives. The sweetening and flavoring agents will increase the palatability of the preparation. Tablets containing the hydrolyzed collagen type II in admixture with non-toxic pharmaceutically acceptable excipients stable for tablet manufacture are acceptable. Such excipients include inert diluents such as calcium carbonate, sodium carbonate, lactose, calcium phosphate or sodium phosphate; granulating and disintegrating agents, such as corn starch or alginic acid; binding agents such as starch, gelatin or acacia; and lubricating agents such as magnesium stearate, stearic acid or talc. Tablets may be uncoated or may be coated by known techniques to delay disintegration and absorption in the gastrointestinal tract and thereby provide a sustained action over a longer period of time. For example, a time delay material such as glyceryl monostearate or glyceryl distearate alone or with a wax may be employed. The use of enteric coatings is also contemplated.

Formulations for oral use may also be presented as hard gelatin capsules wherein the active ingredient is mixed with an inert solid diluent, for example calcium carbonate, calcium phosphate or kaolin, or as soft gelatin capsules wherein the active ingredient is mixed with water or an oil medium, such as peanut oil, liquid paraffin or olive oil.

Aqueous suspensions may contain the hydrolyzed collage type II of the invention in admixture with excipients suitable for the manufacture of aqueous suspensions. Such excipients include suspending agents, dispersing or wetting agents, one or more preservatives, one or more coloring agents, one or more flavoring agents and one or more sweetening agents such as sucrose or saccharin.

Oil suspensions may be formulated by suspending the active ingredient in a vegetable oil, such as arachis oil, olive oil, sesame oil or coconut oil, or in a mineraloil such as liquid paraffin. The oil suspension may contain a thickening agent, such as beeswax, hard paraffin or cetyl alcohol. Sweetening agents, such as those set forth above, and flavoring agents may be added to provide a palatable oral preparation. These compositions may be preserved by an added antioxidant such as ascorbic acid. Dispersible powers and granules of the invention sable for preparation of am aqueous suspension by the addition of water provide the active ingredient in admixture with a dispersing or wetting agent, a suspending agent, and one or more preservatives. Additional excipients, for example sweetening, flavoring and coloring agents, may also be present.

Syrups and elixirs may be formulated with sweetening agents, such as glycerol, sorbitol or sucrose. Such formulations may also contain a demulcent, a preservative, a flavoring agent and/or a coloring agent.

The hydrolyzed collagen type II powder may be mixed with other ingestible forms and consumed in solid, semi-solid solution, suspension or emulsion form. It may also be mixed in conjunction or alternatively with pharmaceutically acceptable carriers, flavor enhancers, water, suspending agents and emulsifying agents. In a preferred embodiment, the hydrolyzed collagen type II powder is mixed with a citrus juice such as orange, grapefruit or tangerine due to the promotion of connective tissue formation by ascorbic acid. The hydrolyzed collagen may also be provided in tablet form in admixture with ascorbic acid.

For use as a nutritional supplement, prophylactic or therapeutic agent, the hydrolyzed collagen is orally administered in a daily dosage of between about 500 mg and 5,000 mg. More preferably, it is administered in a daily dosage of between about 2,000 mg and 4,000 mg. Most preferably, it is administered in a daily dosage of between about 2,000 and 3,000 mg per day. The hydrolyzed collagen type II powder may be formulated into tablets which range from 300 mg to 1,000 mg per tablet. In a preferred embodiment, the hydrolyzed collage type II powder is formulated into 500 mg tablets and 4-6 tablets are taken daily. In another preferred embodiment, the

tablets are taken on an empty stomach with a beverage containing vitamin C.

In another preferred embodiment, the hydrolyzed collagen type II powder is mixed with water or a citrus juice prior to ingestion. The preparations described above can be taken indefinitely by individuals affected by connective tissue disorders or by healthy individuals as a preventative agent. If desired, an individual with such a disorder can take the preparation until no further improvement is noted in the disorder.

The above detailed description of the invention is set forth solely to assist in understanding the invention. It is to be understood that variations of the invention, including all equivalents now known or later developed, are to be considered as falling within the scope of the invention, which is limited only by the following claims.

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United States Patent **6,838,440**
Stiles **January 4, 2005**

Kolla2-desiccated avian sternal cartilage powder

Abstract

Kolla2 powder compositions, method of preparing the compositions and use of the compositions in treating arthritic joint cartilage diseases. The compositions are orally administered to human in need of cartilage cell repair in a daily dietary supplement dosage of between about 2,400 mg and 3,600 mg.

Inventors: **Stiles; Terri Lynn** (Laguna Beach, CA)
Assignee: **Collagen Nutraceuticals, Inc.** (Lake Forest, CA)
Family ID: **25081659**
Appl. No.: **09/768,141**
Filed: **January 24, 2001**

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Current CPC Class:	A23J 1/10 (20130101); A23L 33/17 (20160801); A61K 35/32 (20130101)
Current International Class:	A23J 1/10 (20060101); A23J 1/00 (20060101); A23L 1/305 (20060101); A61K 038/39 ()
Field of Search:	;514/2,21 ;530/536,412 ;435/212,273,68 ;426/32

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U.S. Patent Documents

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5073373	December 1991	O'Leary et al.
6025327	February 2000	Alkayali

Primary Examiner: Wax; Robert A.
Assistant Examiner: Mondesi; Robert B.
Attorney, Agent or Firm: McLaughlin; Craig Levin & O'Connor

Claims

What is claimed is:

1. A method of preparing cartilage-derived material comprising collagen type II in powder form, comprising the steps: (a) cutting avian sternal cartilage to within not less than 2 mm of the sternum and removing the cut sternal cartilage from the sternum; (b) freezing the cut sternal cartilage into frozen cartilage; (c) grinding the frozen cartilage into ground-cartilage; (d) suspending the ground cartilage in an aqueous solution; (e) sterilizing the ground cartilage; (f) filtering the sterilized ground cartilage; (g) defatting the ground cartilage; (h) filtering the defatted ground cartilage; (i) drying the ground cartilage; and (j) milling the dried ground cartilage into powder form.

2. The method of claim 1 wherein the aqueous solution is water.

3. The method of claim 1 wherein the sterilizing step includes heating the ground cartilage to at least 95.degree. C. for at least 30 minutes.

4. The method of claim 1 wherein the defatting step includes treating the ground cartilage with ethanol.

5. The method of claim 1, wherein the drying step includes heating the ground cartilage to at least 95.degree. C. for at least 6 hours.

6. The method of claim 1, wherein the dried ground cartilage is milled into a powder form having a size between about 80 mesh to 200 mesh.

Description

FIELD OF THE INVENTION

The present invention provides a composition useful as a dietary food supplement for treating arthritis by oral consumption by mammals. Said composition comprising Kolla2 extracted from desiccated avian sternal cartilage collagen type II powder, a method of manufacturing Kolla2 powder and its use for arthritis as a therapeutic agent and nutritional food supplements.

BACKGROUND OF THE INVENTION

One of every 3 American over the age of 60 suffers from osteoarthritis. It is a natural wear and tear of joint cartilage. As we age, the body's ability to make the protein Type II Collagen slows down. This is the protein needed to maintain and rebuild cartilage tissue. Collagen is a complex structural protein, which provides strength and flexibility to all connective tissues. Collagen is a major component of muscles, tendons, cartilage, ligaments, joints and blood vessels. There are four main types of collagen: II, III, IV, and I. Type I and III are primarily found in skin, tendon and bone. In contrast, collagen type II is found predominately in articulator cartilage. Collagen is an unusual protein, in that the proportion of glycine residues is nearly one-third which is unusually high. Proline is also present to a much greater extent in collagen that in most other proteins. Moreover, collagen contains two amino acids, 4-hydroxyprolineand 5-hydroxylysine, that are found in very few other proteins. The amino acid sequence of collagen is remarkably regular, nearly every third amino acid is glycine. In addition, the sequence of glycine-proline-hydroxyproline recurs frequently. In contrast, globular proteins rarely exhibit regularities in their amino acid sequences (Stryer, L., Biochemistry, Third Edition, W. H. Freeman and Co., New York, 1988, pp.262).

In 1986, collagen was sold for the first time in the United States for use as a food Supplement. Collagen (a mixture of Types I and Type III) was extracted from calf skin tissue, and prepared in powder form for use as a

dietary supplement.

In 1987, the composition was sold compressed into 1,000 mg. tablets which comprised collagen powder and 10 mg. Vitamin C.

U.S. Pat. No. 4,804,745 to Koepff et al. Discloses agents containing collagen peptides produced by enzymatic hydrolysis for the treatment of degenerative joint diseases. These peptides can be obtained from animal skin, animal bones and other sufficiently purified connective tissue and have average molecular weights of between 30 and 45 kilodaltons.

U.S. Pat. No. 5,399,347 to Trentham et al. And Trentham et al. (Science 261:1727-1729, 1993) disclose the effective treatment of rheumatoid arthritis (RA) with water-soluble whole chick collagen type II or biologically active peptides derived therefrom. The mechanism by which the effect is believed to occur is via oral tolerization.

U.S. Pat. No. 5,364,845 to Henderson discloses a therapeutic composition and method for the protection, treatment and repair of connective tissue in mammals. This composition comprises glucosamine, chondroitin sulfate and manganese ascorbate. U.S. Pat. No. 5,587,363 to Henderson discloses a therapeutic composition and method for the protection, treatment and repair of connective tissue in mammals which includes aminosugars and glycosaminoglycans.

U.S. Pat. No. 6,025,327 to Alkayali discloses a therapeutic composition and method for the protection, treatment and repair of joint cartilage in mammals. This composition comprises hydrolyzed collagen type II water--soluble, denatured collagen type II obtained from chicken sternal cartilage.

The demand for compositions suitable for prevention of degenerative joint disease will surpass the demand of arthritis treatment. The present invention addressed this need.

SUMMARY OF THE INVENTION

The art of the present invention is Kolla2 --desiccated avian sternal cartilage collagen type II powder, the kolla2 powder having an average molecular weight of between about 45,000 and 65,000 daltons. Preferably, the kolla2 has an average molecular weight of about 50,000 daltons. In one aspect of this preferred art, the kolla2 is obtained from desiccated young avian sternal cartilage. Preferably, the avian sternal cartilage is collected from 4-8 week old chicks. The kolla2 is partially water-soluble and the composition comprises 20% to 30% mucopolysaccaride (carbohydrate) and 65% to 70% Collagen type II (protein) and the content of 1% to 3% lipids is part of the kolla2 composition. The present invention also provides a method of helping cartilage formation in Human with a connective tissue disorder, degenerative joint diseases, comprising orally administering to the individual an effective of daily cartilage-inducing amount of kolla2 powder.

The degenerative joint diseases include cartilage injuries, joint defects, rheumatoid arthritis, osteoarthritis, vascular disease, polychondritis, and connective tissue disorder. Preferably, the effective daily dosage amount is between about 600 mg and 10,000 mg. More preferably, the effective daily dosage amount is between about 1,200 and 7,200 mg. Most preferably, the effective daily dosage amount is between 2,400 and 3,600 mg. Another embodiment of the invention is a method of providing kolla2 as a preventative nutritional supplement, comprising orally administering to an individual a daily dosage of kolla2 having an average molecular weight of between about 45,000 and 65,000 daltons.

Stile another embodiment of the invention is a method of preparing kolla2 powder, comprising the following steps: cutting fresh 4 to 8 weeks young chicken sternal cartilage to within not less than about 2 mm of the bone; grinding cartilage into ground mesh, suspending ground cartilage in an aqueous solution; sterilizing said cartilage, filtering the ground cartilage, defatting the ground cartilage, drying the ground cartilage, milling the dried cartilage to form desiccated sternal avian cartilage powder--kolla2.

The method may further comprise the step of deep freezing the cartilage after cutting step. Preferably, the aqueous solution is water. Advantageously, grinding the deep frozen cartilage into ground mesh. In one aspect of this preferred embodiment, the sterilization process step comprises a temperature control at a minimum of 95.degree. C. for a minimum of 30 minutes. Preferably, the drying step comprises a temperature control at a minimum 95.degree. C. for a minimum of 6 hours. Preferably, the milling into powder and the bulk density at 20.degree. C. is approximately about 600 g/l.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of the process for preparing and the manufacturing of kolla2 dissipated sternal avian cartilage powder of the invention.

DETAILED DESCRIPTION OF THE PREFERRED ARTS

The present invention provides a kolla2 desiccated avian sternal cartilage denatured collagen II protein composition, method for preparing the composition and use of the composition in the treatment and repair of cartilage defects, and the prevention of arthritis diseases. The method involves cutting fresh sternal cartilage from 4 to 8 weeks avian carcasses and removing all meat, blood and bone therefrom. The sternal cartilage is cut leaving a space of about two and a half millimeters from the bone so as to not remove any bone fragments. This is essential to the purity of the final product because it avoids contamination of collagen type II protein with types III and I found in bone. The fresh sternal cartilage is then promptly deep-frozen and the remained of the chicken carcass is discarded. It is important the sternal cartilage, cut so no bone is included, that is used for preparing the kolla2 powder, The sternal cartilage is processed according to good manufacturing practice (GMP). Other contemplated sources of collagen type II are mammalian (i.e. bovine and porcine) and shark fins.

The production of kolla2 desiccated avian sternal cartilage in powdered form is shown in FIG. 1. Ground deep-frozen cartilage is suspended in an aqueous solution, preferably water and sterilized at temperature control at about 95.degree. C. for a minimum of 30 minuets. The water is removed by filtration and cartilage mesh is treated with ethanol to remove excess fat, filtration and drying the sternal cartilage at a temperature between about 95.degree. C. for a minimum of 6 hours. The dried sternal cartilage is milled to a fine mesh powdered, preferably bulk density at 20.degree. C. is approximately about 600 g/l. The kolla2 powder is packed in a 50 kg, drum with a plastic bag liner. The powder is partially water-soluble.

The average molecular weight of the final powder is between 45,00 and 65,000 daltons, preferably 50,000 daltons. The final powder product is 20% to 30% mucopolysaccharides, particularly chondroitin sulfate and glucosamine sulfate. The product has 375 calories per 100 grams, contains 65% collagen type II protein (13.1 total nitrogen), and 20% carbohydrate and 2% lipids. Kolla2 powder is ready to be utilized after the human body's superior natural enzyme break down the amino acid chain into the precise genetic code for joint cartilage repair. The natural lipids found in kolla2 together with collagen II protein and carbohydrates constitute the chief structural components of joint cartilage cell. The unique amino acid composition and molecular weight of the kolla2 differs substantially from typical collagen proteins and is shown in Table 1. Tryptophan and hydroxylysine amino acids are absent and hydroxyproline is low. The molecular weight and amino acid composition and the natural lipids which is essential to promote optimal assimilation of the peptides.

When kolla2 is taken orally as a daily dietary supplement by an individual with a degenerative joint disorder, kolla2 helps fabricate cartilage and considerably improves the joint disorder. "Oral" administration includes oral, enteral or intragastric administration. The kolla2 of the invention can be used to trat, for instance, degenerative joint disease (i.e. rheumatoid arthritis), osteoarthritis, cartilage injuries, joint defects, connective tissue disorder, polychondritis, vascular disease, silicone poisoning due to leakage in breast implants, autoimmune diseases involving connective tissue autoantibodies (i.e. rheumatoid arthritis), progressive myopia, menier's disease and any other connective tissue disorder which would benefit from increased synthesis of cartilage.

For oral administration as a nutritional dietary supplement, therapeutic or prophylactic agent, the kolla2 of the invention may be provided as a dispersible powder or granule, tablet, hard or soft capsule, emulsion, aqueous or

oil suspension, syrup or elixir. Compositions intended for oral use may be prepared in accordance with any method known in the art for the manufacturing of nutritional supplement compositions and such compositions may contain one or more of the following components: preservatives, sweeteners, flavoring agents and coloring agents. The flavoring agents and sweetening will enhance the palatability of the preparation. Tablets containing kolla2 in admixture with non-toxic pharmaceutically acceptable excipients suitable for tablet manufacture are acceptable. Such excipients include inert diluents such as calcium carbonate, sodium carbonate, lactose, calcium phosphate or sodium phosphate, granulating and disintegrating agents, such as corn starch or alginic acid, binding agents such as starch, gelatin or acacia; and lubricating agents such as magnesium stearate, stearic acid or talc, Tablets may be uncoated or may be coated by known techniques to delay disintegration and absorption in the gastrointestinal tract and thereby provide a sustained action over a longer period of time. For example, a time delay material such as glyceryl monostearate or glyceryl distearate alone or with a wax may be employed. The use of enteric coating is also contemplated. Formulations for oral use may also be presented as hard gelatin capsules wherein the active ingredient is mixed with an inert solid diluent, for example calcium carbonate, calcium phosphate or kaolin, or as soft gelatin capsules wherein the active ingredient is mixed with water or an oil medium, such as peanut oil, liquid paraffin or olive oil.

Aqueous suspensions may contain the kolla2 powder of the invention in admixture with excipients suitable for the manufacture of aqueous suspensions. Such excipients include suspending agents, dispersing or wetting agents, one or more preservatives, one or more coloring agents, one or more flavoring agents and one or more sweetening agents such as sucrose or saccharin.

Oil suspensions may be formulated by suspending the active ingredient in a vegetable oil, such as arachis oil, olive oil, sesame oil or coconut oil, or in a mineral oil such as liquid paraffin. The oil suspension may contain a thickening agent, such as beeswax, hard paraffin or cetyl alcohol. Sweeting agents, such as those set forth above, and flavoring agents may be added to provide a palatable oral preparation. These compositions may be preserved by an added antioxidant such as ascorbic acid. Dispersible powders and granules of the invention suitable for preparation of an aqueous suspension by the addition of water provide the active ingredient in admixture with a dispersing or wetting agent, a suspending agent, and one or more preservatives. Additional excipients, for example, sweetening, flavoring and coloring agents may also be present. Syrups and elixirs may be formulated with sweetening agents, such as glycerol, sorbitol or sucrose. Such formulations may also contain a demulcent, a preservative, a flavoring agent and/or a coloring agent. The kolla2 powder may be mixed with other ingestible forms and consumed in solid, semi-solid solution, suspension or emulsion form. It may also be mixed in conjunction or alternatively with pharmaceutically carriers, flavor enhancers, water, suspending agents and emulsifying agents. In a preferred embodiment, the kolla2 powder is mixed with a citrus juice such as orange, grapefruit or tangerine due to the promotion of connective tissue formation by ascorbic acid. In a preferred essence, the kolla2 may also be formulated in admixture with ascorbic acid.

For use as a nutritional dietary supplement, prophylactic or therapeutic agent. Kolla2 is orally administered in a daily dosage of between about 600 mg capsule and 10,000 mg. More preferably, it is administered in a daily dosage of between about 3,600-mg and 7,200 mg. Most preferably, it is administered in a daily dosage of between about 2,400 and 3,600 mg. per day. The kolla2 may by formulated into tablets that range from 600 mg. to 1,000 mg. per tablet, In a preferred embodiment, the kolla2 powder is formulated into 600-mg tablets and 4-6 tablets are taken daily. In another preferred embodiment, the tablets are taken on an empty stomach with a beverage containing vitamin C. In another preferred embodiment, the kolla2 powder is mixed with water or a citrus juice prior to ingestion. The preparations described above can be taken indefinitely by individuals affected by connective tissue disorders or by healthy individuals as a preventative agent. The above detailed description of the invention is set forth solely to assist in understanding the invention. It is to be understood that variations of the invention, including all equivalents now known or later developed are to be considered as falling within the scope of the invention, which is limited only by the following claims.

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Exhibit "D"

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United States Patent **8,344,106**
Summers , et al. **January 1, 2013**

Collagen mixture and method of making the same

Abstract

A collagen mixture having a portion of unhydrolyzed eggshell membrane collagen and Avian collagen.

Inventors: **Summers; Dana** (Sioux Center, IA), **den Hoed; Robert** (Sioux Center, IA)
Assignee: **Den Hoed; Robert** (Sioux Center, IA)
Family ID: **47388253**
Appl. No.: **13/197,318**
Filed: **August 3, 2011**

Current U.S. Class: **530/356**
Current CPC Class: C07K 14/465 (20130101); A61K 35/57 (20130101); C12N 9/48 (20130101)
Current International Class: A61K 38/17 (20060101)

References Cited [Referenced By]

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2009/0104173	April 2009	Strohbehn et al.

Primary Examiner: Noakes; Suzanne M
Attorney, Agent or Firm: Zarley Law Firm, P.L.C.

Claims

What is claimed is:

1. A method of making Type II collagen, comprising the steps of: obtaining Avian cartilage in frozen form; thawing the frozen cartilage; adding an enzyme mixture comprising a plant derived proteolytic enzyme, a bacterial proteolytic enzyme and a buffer to the thawed cartilage to break the cartilage down into liquid form; heating the liquid cartilage to form a layer of liquid digest; raising the pH level of the liquid digest; heating the raised pH level liquid digest to 8-11 to form a partial solid content; and spray drying the heated partial solid content.

2. The method of claim 1 wherein the enzyme mixture includes a liquid plant derived enzyme, a bacterial protolitic enzyme, and a buffer.

3. The method of claim 1 wherein the pH level of the liquid digest is raised 8 to 11 pH.

4. The method of claim 1 wherein the heated partial solid content is spray dried using pulse combustion.

Description

BACKGROUND OF THE INVENTION

This invention is directed to creating a collagen mixture and more specifically, without limitation, creating a collagen mixture of unhydrolyzed eggshell membrane with LOS with Avian collagen.

Methods for producing collagen are known in the art. Such collagen is used for many things such as the healing of wounds, the production of skin creams and shampoo, the treatment of osteoarthritis and osteoporosis, and as an additive for human and pet food. While useful, the process is expensive, complicated, involving many steps, and requires harsh chemicals and inorganics which can damage unique properties. Accordingly, a method and mixture is needed in the art that addresses these deficiencies.

An objective of the present invention is to combine Type I, V, and X collagen with Type II collagen.

Another objective of the present invention is to provide a method of making unhydrolyzed eggshell membrane collagen with LOS that involves fewer steps and is unde-natured.

A still further objective of the present invention is to provide a method of producing Avian collagen Type II with a greater molecular weight.

These and other objectives will be apparent to one of ordinary skill in the art based upon the following written description, drawings, and claims.

SUMMARY OF THE INVENTION

A collagen mixture includes a portion of unhydrolyzed eggshell membrane collagen and a portion of Avian collagen. The method of making the eggshell membrane collagen includes separating a membrane from an eggshell, drying the membrane, and pulverizing the membrane into a powder. The method of making the Avian collagen includes adding an enzyme mixture to a thawed Avian cartilage to break the cartilage down into liquid form, heating the liquid cartilage to form a layer of liquid digest, raising the pH level of the liquid digest, heating the raised pH level liquid digest to form a partial solid content, and spray drying the partial solid content.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a flow diagram of a method for making unhydrolyzed eggshell membrane collagen;

FIG. 2 is a schematic diagram of the environment for making unhydrolyzed eggshell membrane collagen;

FIG. 3 is a flow diagram for a method of making a collagen mixture; and

FIG. 4 is a schematic diagram of the environment for making a collagen mixture.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the Figures, the process of making unhydrolyzed eggshell membrane collagen containing Type I, V, and X collagen and lysosyme, ovatransferin, and sialic acid (LOS) begins at step 100 by obtaining sanitized cracked eggshells 10. The cracked eggshells 10 are placed on a sifter 12 at step 110 where the membrane 14 of the eggshell 10 is separated from the shell 10. The sifter 12 is of any type and preferably includes a fine mesh through which the shell 10 falls while the membrane 14 is transported to the end of the sifter 12.

Once separated, the membrane 14 is placed in a hot dryer 16 to dry the membrane and kill bacteria at step 120. While the dryer 16 is of any type, a motion dryer is preferred to facilitate faster drying. Once dried, the membrane 14, which is in flake form, is pulverized into a powder at step 130. Once in powder form, the membrane is packaged preferably in a fiber drum or bag for further use and/or processing.

The process of making the Avian collagen with LOS begins by obtaining Avian cartilage 18, typically in frozen form at step 200. At step 210, the frozen cartilage 18 is thawed by placing the cartilage in a tank 20 containing hot water. Once thawed, an enzyme mixture 22 is added to the thawed cartilage 18 which breaks the cartilage down into liquid form at step 220. Preferably, the enzyme mixture 22 includes a liquid plant derived enzyme 24 such as papain, ficen, or bromalain; a bacterial proteolytic enzyme 26, such as acid, neutral, or alkelian; and a buffer 28 such as acetic acid or sodium hydroxide and water for a pH buffering range of 4.8 to 6.8. As the enzyme mixture 22 breaks down the cartilage 18, the tank is heated to preferably 140.degree.-160.degree. F. such that the cartilage 18 separates into a top layer of fat 30, a middle layer of liquid digest 32, and a bottom layer of bone chips 34.

Once separated, at step 230, the bone chips 34 are swept away from a valve 36 in the bottom of the tank 20 and the liquid digest 32 is pumped through the valve 36 to a holding tank 38. Once pumped, at step 240, the pH level of the liquid digest 32 is raised by adding sodium hydroxide or potassium hydroxide 40 to the liquid digest 32 in the holding tank 38. Preferably the pH level of the liquid digest 32 is raised to a level of 8 to 11.

At step 250, after the pH level is raised, the liquid digest 32 is pumped into an evaporator 42 where the liquid digest 32 is heated to a solid content of between 10% to 75% such that the liquid has a syrup consistency. Preferably the liquid digest is heated at a temperature of 200.degree.-230.degree. F. to create a solid content of 35-40%.

Next, at step 260, the solid liquid digest 32 is transported to an area for spray drying 44. Preferably, the solid liquid digest is spray dried using pulse combustion. Also, a carrier such as multrodextrine is added to assist in pulling off extra water from the liquid digest 32. This results in a dry powder comprised of Avian collagen.

Once the Avian collagen has been spray dried it is mixed with the unhydrolyzed eggshell membrane collagen at step 270 to create a blended collagen mixture that includes Type I, II, III, IV, V and X collagen and LOS. Preferably the mixture has 70% Avian collagen to 30% eggshell membrane or alternatively 30% Avian collagen to 70% eggshell membrane collagen. Once combined, at step 280, the mixture is packaged and distributed.

Accordingly, a collagen mixture and method of making the same has been disclosed that, at the very least, meets all the stated objectives.

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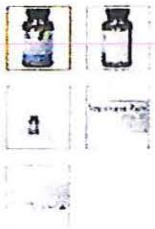



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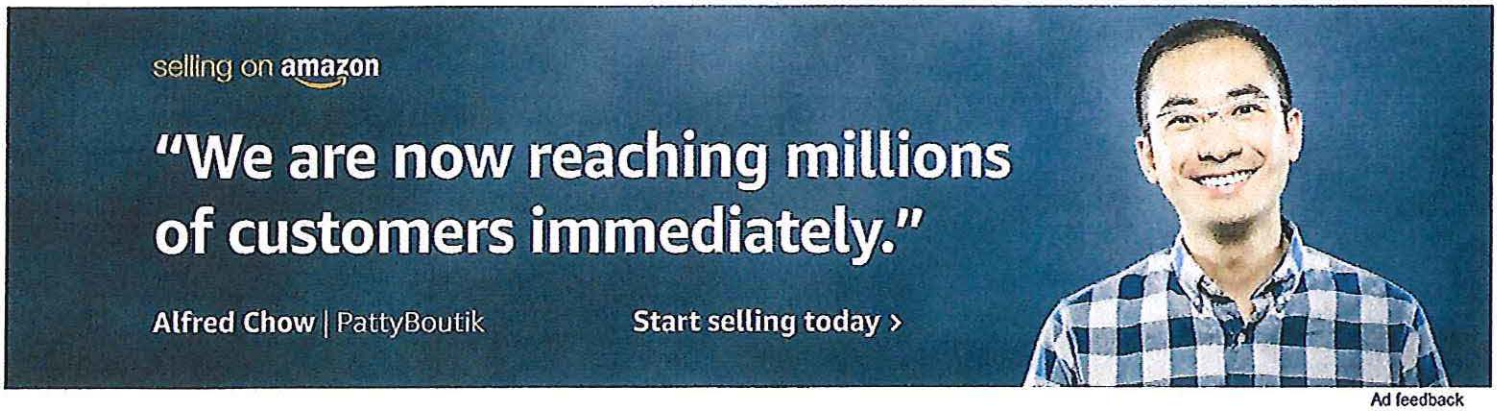

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Completely misleading in the ad copy on this Amazon page. I don't know if it's Amazon writing the copy or if it's Neocell (the vendor), but some representative of either should take a look at the bogus misrepresentation that twists & turns around the copy point saying this stuff comes from (it doesn't say contains anywhere) Rooster Comb. Heck, just look at the product description on the header of this review: "Neocell Hyaluronic Acid From Rooster Comb." Look at the heading of the top of the page: "Neocell Hyaluronic Acid From Rooster Comb." Look at the bulletpoint under the heading: "Pure hyaluronic acid carefully sourced from external tissue, rooster comb."
I bought this supplement because of all the health accolades associated with rooster comb products. I imagine many of you have done or are about to do the same. Well, don't buy this Neocell Hyaluronic Acid if that's what you're hoping to find. I was a sucker and I typically don't fall for misleading advertising -- especially after so many here warned about the b.s. in their own reviews. Trust me, there is nothing (NOTHING) on the jar labeling that says rooster comb. It doesn't even hint at it. I could go on, but you get the point.
I've not opened the jar. It's still sealed. I'm returning it after this gets posted.

Comment 96 people found this helpful. Was this review helpful to you? Yes No Report abuse

Ad feedback

Most Recent Customer Reviews

A good decision
You get the best results with these when taken with the Super Collagen 1&3 +C. (Also made by NeoCell) But you probably don't have to stick with that brand. Read more
Published 18 days ago by Shopping Junkie

Great product!! Skin has greatly improved!!
Love this stuff! I take this along with my collagen and bone broth...and let me tell you, my skin, hair and nails are as good as I've ever seen and I'm 56!! Read more
Published 18 days ago by Cheryl

Five Stars
Great product! Read more
Published 1 month ago by Dinch

Great product
Good product. Must take recommended dose Read more
Published 1 month ago by christine Seifert

Easy to Take
Easy to take capsules that arrived intact and as promised. Now I hope they work as promised:) I have been told to give them a few months to show a noticeable difference in skin... Read more
Published 1 month ago by Beachreader

Neocell Hyaluronic Acid, 100 Mg
Wonderful product! Read more
Published 1 month ago by datak

This product is NOT made of ROOSTER COMB. I ...

By RT on December 22, 2014
Size: 60 Verified Purchase

This product is NOT made of ROOSTER COMB. I spoke to someone from Neocell today. I was told this product IS MADE FROM GLUCOSE FIRMENTATION OF NON GMO CORN.

Comment 85 people found this helpful. Was this review helpful to you? Yes No Report abuse

Not being honest.

By Susan F on January 16, 2016
Size: 60 Verified Purchase

Not being honest. It says 60 capsules on the bottle, but there are only 56 inside. Although not a big difference, but I can't help feeling being cheated. Be aware!

Comment 59 people found this helpful. Was this review helpful to you? Yes No Report abuse

False advertising: these pills contain 50mg

By Quantum Meruit on September 1, 2015
Size: 60

A reasonable person would think that each pill contains 100mg, given the large "100 mg" on the front of the bottle and on the Amazon page. However, a close read of the back label reveals that 100mg is the "Daily intake per 2 capsules." So each capsule is 50mg, making this twice as expensive as other brands. I've never seen a supplement dosage advertised in such a confusing and misleading way.

1 comment 71 people found this helpful. Was this review helpful to you? Yes No Report abuse

Love/Hate this product.

By Step Lively on August 7, 2015
Size: 60 Verified Purchase

This will make your skin glow. Just marvelous. BUT when you run out . . . oh my goodness. Your skin will be so dry that it is painful and is worse than if you had never used it. If you don't mind taking a product forever, then this is awesome. If you decide to stop you need to s-l-o-w-l-y stop and allow your body to start producing its own HA again. If you do not, you will regret it.

Comment 39 people found this helpful. Was this review helpful to you? Yes No Report abuse

Doesn't work like Swansons Brand!

By Forgiven on March 11, 2014
Size: 60 Verified Purchase

I tried this Hyaluronic Acid from Neocell, but they didn't work for me. I went back to Swanson's Brand because they work for my osteoarthritis.

Comment 44 people found this helpful. Was this review helpful to you? Yes No Report abuse

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Write a customer review

Good stuff

I take 2 Neocell Super Collagen type 1 and 3 twice a day with 1 Neocell Hyaluronic Acid twice a day, and 1 Carlson Elite Omega-3 twice a day. Read more
Published 1 month ago by Amazon Customer

I have only been taking these since April 1st. ...

I have only been taking these since April 1st. I'm taking them in combination with the hyaluronic acid and the biotin chews. Read more
Published 1 month ago by Suz

Five Stars

easy to take Read more
Published 1 month ago by Dee

Five Stars

This stuff has helped my knee pain quite a bit. Read more
Published 2 months ago by anita whaley

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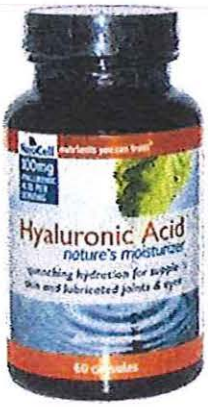
Neocell Super Collagen+C Type 1 and 3, 6000mg plus Vitamin C, 250 Count

Neocell, Hyaluronic Acid, Nature's Moisturizer, 60 Capsules

By Neocell

★★★★★ 148 Reviews





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- Expiration Date: ? Sep 2019
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- Product Code: NEL-09664
- UPC Code: 016185096646
- Package Quantity: 60 Capsules
- Dimensions: 2.4 x 2.4 x 4.3 in, 0.1 lbs

Bundle Offer Save $4.01 when you purchase these items today for only $23.00



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Madre Labs, DHA 700 Fish Oil, Pharmaceutical Grade, German Processed, No...

★★★★★ 60

$8.00

Total: $27.01
Combo Discount: - $4.01
Together: $23.00

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Related Products

1 of 5







Madre Labs, Camellia Care, EGCG Green Tea Skin Cream, Anti-Aging, Moisturizing and Hydrating, 1.7 fl oz (50
★★★★★ 709
$9.00

California Gold Nutrition, CollagenUP™ 5000, Marine-Sourced Collagen Peptides + Hyaluronic Acid & Vitamin C,
★★★★★ 382
$25.00

California Gold Nutrition, CollagenUP™ 5000, Marine-Sourced Collagen Peptides + Hyaluronic Acid & Vitamin C,
★★★★★ 418
$12.00

Product Overview

Description

- Nutrients You Can Trust
- 100 mg Hyaluronic Acid Per Serving
- Quenching Hydration for Supple Skin and Lubricated Joints & Eyes
- Dietary Supplement
- Eye Health
- All Natural
- Joint Health
- GMP Certified
- Skin Viscoelasticity

Hyaluronic Acid (HA) is an important disaccharide found in every tissue of the body, in particular as an essential lubricant of healthy joints, skin and eyes. Hyaluronic Acid promotes cell turnover and is known as Nature's Moisturizer due to its ability to hold up to 1000 times its weight in water.

Suggested Use:

Suggested Use

As a dietary supplement, take 1 capsule twice daily on an empty stomach and wait 20 minutes before eating.

Other Ingredients

Vegetable magnesium stearate, kosher gelatin capsule, natural silica and cellulose

Does Not Contain: Soy, wheat, lactose, starch, yeast, or artificial flavors. Gluten Free.

Warnings

Keep out of reach of children. If you are pregnant, nursing, or have a medical condition, consult your physician before taking this product

Visit Manufacturer's Website

Supplement Facts

Serving Size: 2 capsules (100 mg)

Servings per Container: 30

	Amount per serving	%Daily Value
Hyaluronic Acid	100 mg	†

† Daily Value not established

iHerb Customer Reviews

Customer Ratings (148)

★★★★★ 4.45 Stars

5 Star	0%	(102)
4 Star	0%	(24)
3 Star	0%	(12)

TOP POSITIVE REVIEW

★★★★★

Hyaluronic Acid- Neocell 100 mg

Posted by Reviewer3084493 on Feb 15, 2011

Dry eyes are gone, and pain in my joints greatly diminished. I ran out

2 Star	0%	(6)
1 Star	0%	(4)

and went several days without it, before recognizing why I was having so much pain. Won't make that mistake again!

8 people found this helpful

★★★★★

Important

Posted by 4744527862166240677 on May 30, 2017 | Verified Purchase

An important supplement as all neocell supplements it is my 6 bottle

Share Review

Was this review helpful to you?

Yes (0) No (0)

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★★★★★

I love

Posted by 5557390559324403243 on May 08, 2017 | Verified Purchase

A vitamin that is very good.

Share Review

Was this review helpful to you?

Yes (0) No (0)

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★★★★★

Great for the joint

Posted by 5269200402434929207 on Apr 29, 2017 | Verified Purchase

Worked very well for my knee & my wife's knee....No more pain after 3 months.

Share Review

Was this review helpful to you?

Yes (0) No (0)

Report Abuse

★★★★★

Make my skin better

Posted by 5457602648406653336 on Apr 28, 2017 | Verified Purchase

Smoother skin from this produce, suitable for dry and problem skin

Share Review

Was this review helpful to you?

Yes (0) No (0)

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★★★★★

Very satisfied:-)

Posted by 5499266797268987019 on Apr 13, 2017 | Verified Purchase

Very satisfied, reached and exceeded all expectations from the product

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Was this review helpful to you?

Yes (0) No (0)

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Solgar, Isoflavones, with Genistein and
★★★★★ 24
$31.42
United States


Nubian Heritage, Raw Shea Butter
★★★★★ 1555
$3.99
United States



Jarrow Formulas, Bilberry +
★★★★★ 178
$22.63
Hong Kong


YumEarth, Soft Eating Gluten-Free
★★★★★ 32
$2.90
United States


Natrol, AcaiBerry Diet, Acai & Green
★★★★★ 2600
$7.18
Saudi Arabia


Now Foods, Methyl B-12, 1,000 mcg.
★★★★★ 181
$6.74
United States


Shea Moisture, Baby Wash &
★★★★★ 332
$7.67
United States

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Neocell Collagen Type 2 Immucell , 2400 Mg, 120 Count (3 Pack) NEOCELL LABORATORIES

1 customer review



Price: $55.00 & FREE Shipping
Note: Not eligible for Amazon Prim

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Get it as soon as June 13 - 16 wher
Shipping at checkout.

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Honest Herbal Support for Healthy Skin & Joints

Activa Naturals Collagen Type 2 Hydrolyzed 1000mg Supplement with Chondroitin Sulf...

107

$59.95 $24.95 Prime

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Frequently bought together



Total price: $74.00

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This Item: Neocell Collagen Type 2 Immucell , 2400 Mg, 120 Count (3 Pack) $55.00

Neocell Collagen Type 2 Immucell Complete Joint Support Capsules, 2400 Mg, 120 Count $19.00 ($0.16 / Count)

Customers who bought this item also bought

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Neocell Collagen Type 2 Immucell Complete Joint Support Capsules, 2400



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Neocell Collagen Type 2 Immucell Complete Joint Support Capsules, 2400



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Product details

Item Weight: 12 ounces

Shipping Weight: 12 ounces (View shipping rates and policies)

ASIN: B00W226GAC

UPC: 683615374256 767674172791

Average Customer Review: (1 customer review)

Amazon Best Sellers Rank: #346,374 in Health & Household (See Top 100 in Health & Household)
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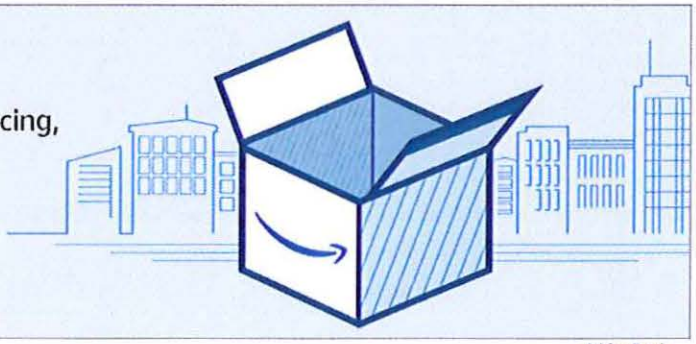

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Typical questions asked about products:

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- Is this item easy to use?
- What are the dimensions of this item?

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4.0 out of 5 stars

5 star		0%
4 star		100%
3 star		0%
2 star		0%
1 star		0%

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$5.00 off coupon
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Top Customer Reviews

I haven't been using this long enough to give it ...

By nanabear on November 12, 2015

Verified Purchase

I haven't been using this long enough to give it above a 4. 3 weeks is not long enough to get significant results,but my joints ARE improving.

Comment Was this review helpful to you? Yes No Report abuse

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Carlson Labs Vitamin K-2, 5mg, 180 Capsules
149
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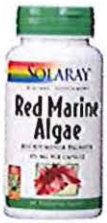
20
$21.95



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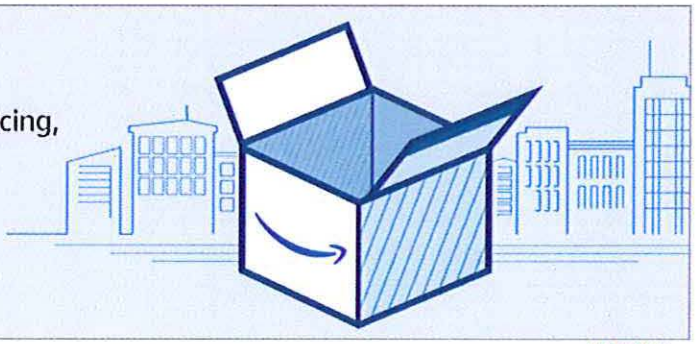

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Neocell Collagen Type 2 Immucell Complete Joint Support Capsules, 2400 Mg, 120 Count Neocell

336 customer reviews | 39 answered questions





About the product

- Immucell collagen type 2 is a complete joint support supplement made of 100% pure collagen type II from chicken sternal cartilage Available in 600 mg capsules as a complete joint supplement
- Naturally contain collagen type II protein, and hyaluronic acid, glucosamine, and chondroitin; these components naturally provide all necessary components for maintaining healthy joints
- Provides the most abundant and essential building blocks for maintaining healthy articular cartilage

Report incorrect product information

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Subtotal: $25.06

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$25.06 Prime

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- **This item:** Neocell Collagen Type 2 Immucell Complete Joint Support Capsules, 2400 Mg, 120 Count $19.00 ($0.16 / Count)
- Neocell Super Collagen+C Type 1 and 3, 6000mg plus Vitamin C, 250 Count $14.99 ($0.06 / Count)
- Neocell Hyaluronic Acid, 100 Mg, 60 Count $17.24 ($0.29 / Count)



Try Great Lakes Gelatin's Collagen Hydrolysate

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Ad feedback



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128
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Ad feedback

Customers who bought this item also bought



Neocell Super Collagen+C Type 1 and 3, 6000mg plus Vitamin C, 250 Count
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$14.99 Prime

Special offers and product promotions

Size: **120**

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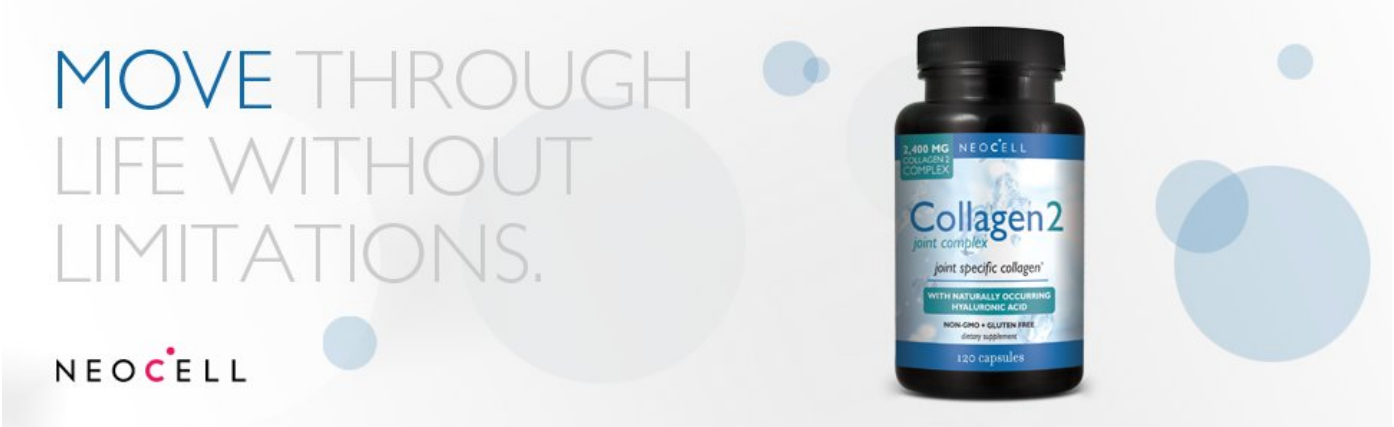
From the manufacturer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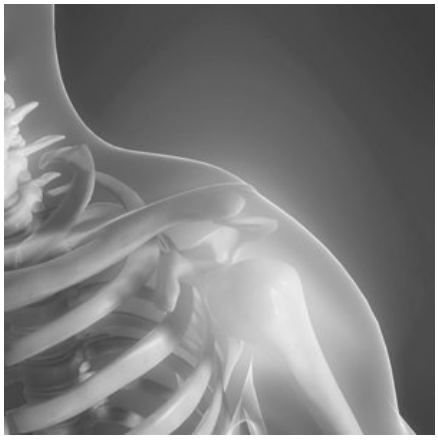
Experience the Benefits







Joint Mobility

- Provides the most abundant and essential building blocks for maintaining healthy articular cartilage.

- Increased range of motion.

- Naturally occurring glucosamine and chondroitin.

Comforting Hydration

- Supports fluid joint movement.

- Assists in joint lubrication.

- Naturally occurring hyaluronic acid.

Cushioning Relief

- May help with joint swelling.

- Helps replenish lost collagen supply.



Product description

Size: **120**

Immucell collagen type 2 is a naturally complete joint support supplement made of 100% pure collagen type II from chicken sternal cartilage. Available in 600 mg capsules as a complete joint supplement. Laboratory tested to naturally contain collagen type II protein, and hyaluronic acid, glucosamine, and chondroitin; these components naturally provide all necessary components for maintaining healthy joints. Provides the most abundant and essential building blocks for maintaining healthy articular cartilage. As dietary supplements take 4 to 6 capsules a day with orange juice or vitamin C drink.

Product details

Size: **120**

Product Dimensions: 4 x 2 x 2 inches ; 4 ounces

Shipping Weight: 4 ounces (View shipping rates and policies)

Domestic Shipping: Currently, item can be shipped only within the U.S. and to APO/FPO addresses. For APO/FPO shipments, please check with the manufacturer regarding warranty and support issues.

International Shipping: This item can be shipped to select countries outside of the U.S. Learn More

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Item model number: 821355

Average Customer Review: ★★★★☆ (336 customer reviews)

Amazon Best Sellers Rank: #2,535 in Health & Household (See Top 100 in Health & Household)
#15 in Health & Household > Vitamins & Dietary Supplements > Minerals > **Collagen**

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Customer Reviews

4.1 out of 5 stars 336

5 star	63%
4 star	11%
3 star	11%
2 star	6%
1 star	9%

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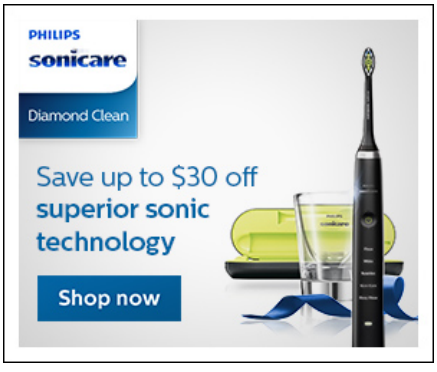
Top Customer Reviews

Type 2 Collagen and my joints: I highly recommend!

By Tony on February 9, 2014

Size: 120 | Verified Purchase

I'm 50, very active, and had been experiencing more soreness in my elbows, hands and knees. It was getting so bad that the soreness/stiffness was making me not want to exercise anymore. I researched collagen as part of my master's program and eventually figured out there are over two dozen types, but for our concern, types I, II and III. I & III is prevalent in many types of connective tissue including the skin, but Type II is more joint specific. I took a bottle of this as directed for my knees (I have a torn meniscus) and, quite surprisingly, noticed that my



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elbows had stopped hurting. I finished the bottle, but looked for something a little easier since taking these meant I was having a glass of orange juice to wash down six capsules every morning, and then waiting a while to eat. I switched to a high quality powdered collagen that I could add to my hot coffee or tea hoping the same results would continue. Indeed, hair and skin quality did improve with the powder, but gradually my aches in my joints came back. I even wrote manufacturers why they wouldn't sell Type II as a powder supplement, but was told something nebulous like "Well, customers prefer capsules." I then actually kind of forgot about the Type II capsules. A few months passed and my elbows and knees and occasionally wrist began giving me problems and I was frankly a bit demoralized, thinking it would take me forever to warm up my joints before exercising again, and I saw I had a half bottle of this left. I took six capsules that evening with some tea (acidic) and six capsules the next morning with coffee (acidic). It wasn't 24 hours before I noticed an almost startling difference in my elbows and knees. "Wow!" was all I could think. I immediately ordered a subscription, and reasoned: a) this

3 comments | 58 people found this helpful. Was this review helpful to you? Yes No Report abuse

Two Stars
By Cathy Frank on December 5, 2015
Size: 120 | Verified Purchase

Product arrived quickly but a bunch of the capsules were only filled half way.



Comment | 29 people found this helpful. Was this review helpful to you? Yes No Report abuse

Will continue to buy
By Ann on November 1, 2013
Size: 120 | Verified Purchase

My nutritionist in Pineville Missouri told me that at my age, almost 94 (and active) that this was a product for my aching legs and my entire body. However it works, I do feel more energetic. I can weed and do yard work daily without feeling exhausted and still be ready to drive to church on Sunday.

Comment | 28 people found this helpful. Was this review helpful to you? Yes No Report abuse

I would give it "0 stars" since I wasted time waiting for supplement
By Robert on November 26, 2016
Size: 120 | Verified Purchase

The picture of the label is misleading. On the website the label showed under OTHER INGREDIENTS ONLY Kosher gelatin capsule. That is why I ordered it. What a big surprise I had when I received the supplement. This product has magnesium stearate and stearic acid. I would give it "0 stars" since I wasted time waiting for supplement. I was refunded and had no problem with customer service.
If you have problem with magnesium stearate do not buy it. I 'm VERY disappointed with NEOCELL. Why do they need to put garbage (magnesium stearate) in their supplements???

Comment | 16 people found this helpful. Was this review helpful to you? Yes No Report abuse

Joints feel better after extended period of using this
By D. Eckman on May 30, 2015
Size: 120 | Verified Purchase

I've rated this product 5 stars because I believe it's helping keep my shoulder, hip and knee joints lubricated and protected, although I have no way to gauge what it's doing except that my knees don't pop, my shoulders don't hurt despite the exercises I do, and my hips feel generally better. I've been using it a year or more, and the improvements were not immediate.

Comment | 4 people found this helpful. Was this review helpful to you? Yes No Report abuse

DISGUSTING! Hair Found in Capsule: Please Read
By Marconi_314 on May 2, 2017
Size: 120 | Verified Purchase

After reading a number of reviews that said that many of the capsules are only partially filled, I can now confirm that those observations are completely true. I would estimate that 1 in 5 capsules are only 50% - 70% full. HOWEVER, what prompted me to write this review was what I saw when emptying a few capsules into my hand.

Please note the picture I took of A HAIR that had been caught between the halves of one of the capsules! It is plain to see that this wasn't just a hair that had fallen in from my head. One end of it is actually locked in the capsule!! In all my years of taking capsules, I've never seen this. It is ABSOLUTELY DISGUSTING and I'd

Most Recent Customer Reviews

Five Stars
Exactly what I was looking for. Will continue to purchase! Read more
Published 18 hours ago by Donna Anderson

Relieved soreness from running; highly recommend.
I started taking these because of sore and aching joints from running a few miles a week. They've made a noticeable and dramatic improvement, and I will definitely continue using... Read more
Published 1 day ago by A. J. Weaver

Love it!
Love it !!! after using it for 2 weeks i started feeling my joints a lot better. . . 5 stars hands down!!! plus i believe that marine collagen must be better than bovine source. Read more
Published 2 days ago by Amazon Customer

Like Collagen 2
Packaging was good and delivery was as promised. I do think this is a superior product. I will most likely continue to take this for a long time. Read more
Published 4 days ago by Rhonda Rumbaugh

Easy to take
Easy to take, haven't noticed anything yet. I'm only taking it once a day because I forget to take it later in the day. Read more
Published 8 days ago by Stacey

... an injury in a knee and says she feels great with only a couple weeks
My mother takes them because of an injury in a knee and says she feels great with only a couple weeks. Read more
Published 9 days ago by Marshmellow

Five Stars
Great product for a good price Read more
Published 13 days ago by Marie Mccullom

Five Stars
Great product for joints Read more
Published 20 days ago by Jesus

Purchase them as gift for others
I purchase these as gift for my parents. They like it and think that it does help with their joints. Read more
Published 29 days ago by Jeff C.

Two Stars
Only has type II collagen & too expensive for the amt of pills/having only 1 type of collagen. Read more
Published 1 month ago by Jasmine D.

Search Customer Reviews
Search

encourage anyone considering purchasing this product to seriously consider another brand.



Comment | 12 people found this helpful. Was this review helpful to you? Yes No Report abuse

Back is much better
By Scarlett(MA) on March 13, 2014
Size: 120 | **Verified Purchase**

I had horrible pain in my back with popping along spine as well as painful knee. Within a weeks use the pain subsided greatly! After two months I rarely have any! Great product!

Comment | 12 people found this helpful. Was this review helpful to you? Yes No Report abuse

Has helped a TON with my broken foot & torn ligament
By Jennifer F on April 14, 2013
Size: 120 | **Verified Purchase**

I am only 28, and I broke my foot and tore a ligament over a year ago. I haven't had much relief until I used this product. I have a much better range of motion and I can actually go days without dwelling on how much my foot hurts because it's SO much better. I guess it's helping with my torn ligament issue more so than the bone. I'm not too sure, I just know it is AMAZING. Also, my grandpa (mid 80s), took this for his knee after he had the other knee repaired surgically. He said that if he knew about this product before, he would have NEVER had surgery. His non-fixed knee feels comparable to his surgically repaired knee, just because he has been taking collagen type 2.

Comment | 49 people found this helpful. Was this review helpful to you? Yes No Report abuse

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This item: Neocell Collagen Type 2 Immucell Complete Joint Support Capsules, 2400 Mg, 120 Count

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Exhibit “F”



Collagenesis™

Product Information

Collagen

Collagenesis™ (collagen) is a naturally occurring protein found in connective tissues. Collagen is a fibrous matrix protein that gives our skin and tendons integrity and elasticity. Vesta's Collagenesis™ is of the highest purity from all natural sources, thus helping our customers to provide one of the highest quality material out on the market.

- Vesta Ingredients has been a leading manufacturer and distributor in the nutraceutical industry for over 15 years. The superior quality of Vesta Brand raw materials has always been the primary driving force of our business and the success of our clientele.

- Collagenesis™ is an all natural raw material product that provides a multitude of health benefits to your hair, eyes, nails, joints, and skin. Vesta offers three collagen forms: collagen type-I, type-II and type-III. Each type naturally occurs in the human body, offering different health benefits.

- Healthy, youthful skin has ample numbers of fibroblasts to help produce a collagenous network within the dermis (middle layer of the skin), but as we age, the number of fibroblasts begin to reduce, leading to less collagen production. This decrease in collagen production is what leads to the formation of wrinkles and sagging skin. Fortunately, this loss of collagen can be supplemented through oral and topical applications.



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WHY USE COLLAGENESIS™?

Collagen is a common protein that is naturally made by our bodies. In fact, it makes up approximately 25%-35% of our entire body's protein content. There are even different forms of Collagen that are incorporated into joints (hyaline cartilage), eyes, skin, nails, hair, and skin. Vesta's Collagenesis™ provides a variety of all natural collagen types. Collagenesis™ is produced through an advanced manufacturing technique that allows us to extract the exact forms of collagen which are the same as those incorporated naturally in the human body.

BENEFITS OF COLLAGENESIS™

- All natural forms of collagen, identical to the kind found naturally in humans
- Helps firm and improve skin elasticity, aiding in wrinkle reduction
- Provides and helps maintain a more youthful appearance

EFFICACIES

- Helps rebuild lost dermal framework caused by aging
- Reduces wrinkles/Increases smoothness
- Revives and rejuvenates complexion
- Firms and improves skin elasticity
- Maintains youthful appearance

PACKAGING AND STORAGE

- Store in cool dry place
- Minimum Pack Size: 1-25kg

Vesta®

Vesta Ingredients, Inc.
5767 Thunderbird Rd.
Indianapolis, IN 46236
USA
Ph: (317) 895-9000, 888-55-VESTA
Fax: (317) 895-9340
info@vestaingredients.com
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Innovative Products at Competitive Prices™

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Exhibit "G"


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for Joint Health
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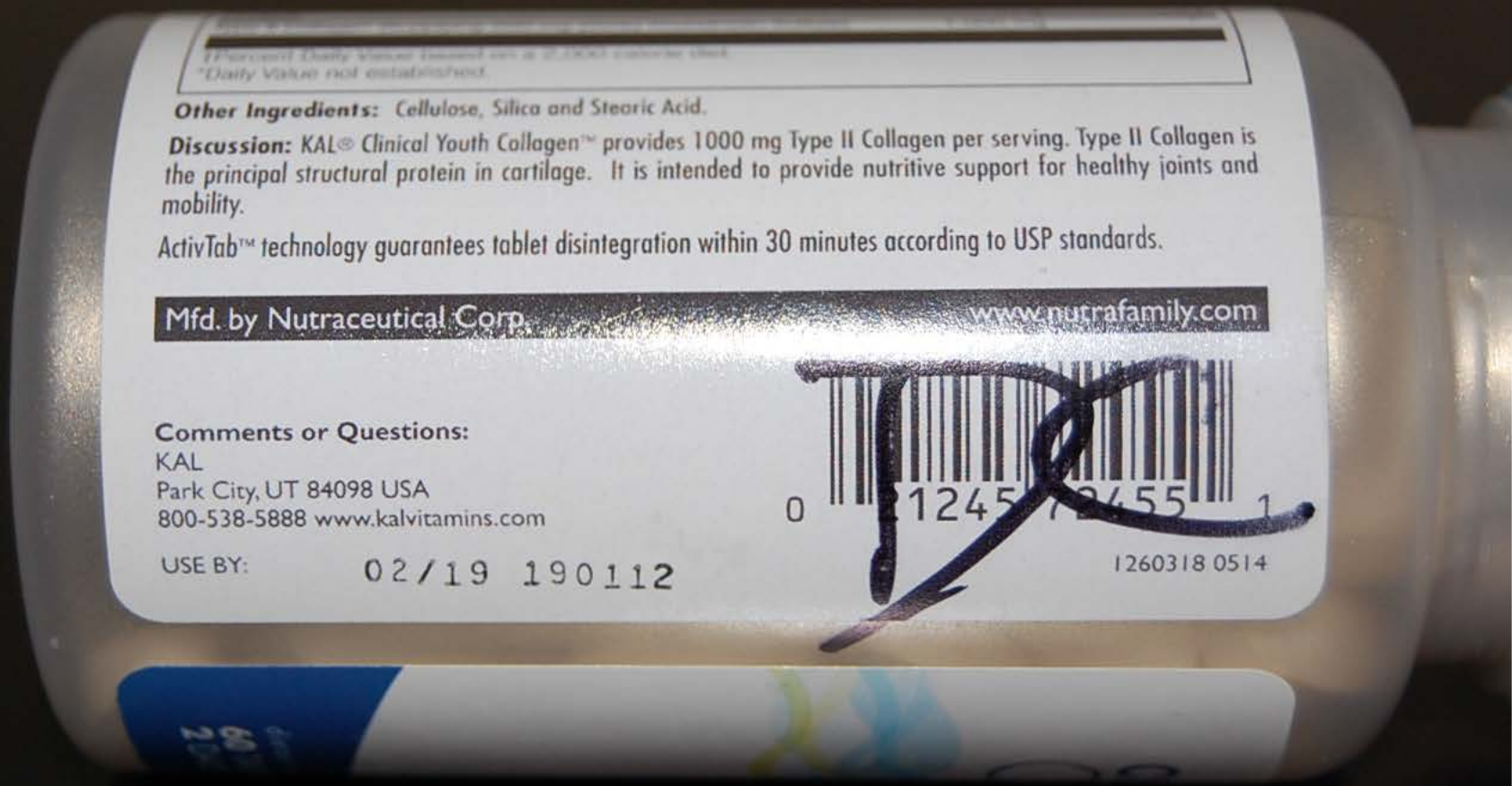
*Daily Value not established.
Other Ingredients: Cellulose, Silica and Stearic Acid.
Discussion: KAL® Clinical Youth Collagen™ provides 1000 mg Type II Collagen per serving. Type II Collagen is the principal structural protein in cartilage. It is intended to provide nutritive support for healthy joints and mobility.
ActivTab™ technology guarantees tablet disintegration within 30 minutes according to USP standards.
Mfd. by Nutraceutical Corp.
www.nutrafamily.com
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Exhibit “H”

VIBRANT HEALTH®

JOINT VIBRANCE®

TASTES GREAT! NEW + IMPROVED! VERSION 5.0

Supplement Facts

Serving Size 1 scoop (18.3g)
Servings per container About 21

Amount per serving	% Daily Value
Calories 70	
Calories from fat 5	
Total Fat 0.5 g	1%**
Total Carbohydrate 5 g	2%**
Dietary fiber 1 g	4%
Protein 11 g	22%**
Vitamin C (ascorbic acid) 100 mg	167%
Calcium 192 mg (from lactate & other ingredients)	19%
Iron 4 mg	22%
Magnesium 79 mg (from lactate & other ingredients)	20%
Zinc (from citrate) 10 mg	67%
Manganese (from citrate) 5 mg	250%
Sodium 130 mg	5%**
Potassium 470 mg	13%**
Silica (from Horsetail Stem ext.) 3 mg	*
CARTILAGE BUILDERS	
Type 1 (Bovine) hydrolyzed collagen 8.6 g	*
Type 2 (Avian) hydrolyzed collagen 2 g	*
Glucosamine hydrochloride 98% (Crustacean) 1.5 g	*
Chondroitin sulfate A 90% (bovine) 1 g	*
Hyaluronic acid 95% 120 mg	*
ANTIOXIDANTS/FLEXIBILITY FACTORS	
MSM (methylsulfonylmethane) powder 1 g	*
Calcium fructoborate 2.5% providing 3 mg boron 120 mg	*
Boswellia serrata gum 20% AKBA extract (ApresFlex®) 100 mg	*
CurcuWIN™ Turmeric *Curcuma longa Rhizome* ext. (20% Curcuminoids) 100 mg	*
Bromelain 2400 GDU/g (from pineapple stem) 100 mg	*
Grape seed 95% polyphenols/ 40% OPCs standardized extract 25 mg	*

**Percent Daily Values are based on a 2,000 calorie diet
*Daily Value not established

Other Ingredients Natural Orange Pineapple Flavor (655mg), Citric acid Powder (500mg), Yacon (Smallanthus sonchifolius) root powder (320mg), Stevia rebaudiana leaf extract certified organic (135mg), Sunflower lecithin powder Non-GMO (100mg)

***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease**

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Joint Vibrance is intended for regular daily use in maintenance of healthy joint function. No other formula is as complete! It takes more than just one ingredient to repair joints. Some only rehydrate; others only support connective tissue. Joint Vibrance combines botanical extracts, specific minerals, powerful nutrients and much more to restore joint function and structure.* As an added benefit, watch fine lines & wrinkles fade, and hair and nails grow longer and stronger.

Directions Once a day as a dietary supplement, mix 1 scoop (enclosed) of Joint Vibrance into 4 to 8 oz. of water, diluted fruit juice or your beverage of choice. Stir briskly or blend in a shaker bottle. Best taken between meals to maximize absorption of nutrients.

Also Available in Tablets, 252 count (JVT)



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This product is not intended to diagnose, treat, cure or prevent any disease.

THE MOST COMPLETE

Joint Formula



TASTES GREAT! NEW + IMPROVED! VERSION 5.0

Rehydrates + Rebuilds + Reduces with:

- ☑ Over 10,500mg of Type 1 & Type 2 Collagen
- ☑ 1000mg of Methylsulfonylmethane
- ☑ 1500mg of Glucosamine HCL
- ☑ 1000mg of Chondroitin Sulfate A
- ☑ 120mg of Hyaluronic acid
- ☑ and much more!*



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Look What's Inside

Joint Vibrance Builds Healthy Joints. No other formula is as complete.

Arthritis, sports injuries, repetitive motion on the job, sprains and strains give nearly everyone some degree of cartilage breakdown by the age of 32 to 35.

Joint Vibrance provides cartilage building cells (chondrocytes) with the proper nutrients necessary for construction of new cartilage and synthesis of hyaluronic acid. As we age, chondrocyte activity slows and eventually fails to adequately compensate for the daily wear and tear placed on joints by an active lifestyle.

Today's science has shown us that the function of chondrocytes can be sustained as long as their nutritional requirements are met. Cartilage can be brought back to greater levels of health, strengthened and thickened if proper nutrients are supplied. There is one controlling principle in the effort to rebuild cartilage: There must be some cartilage with viable chondrocytes in the joint in order for repair to proceed.

The Collagens

Two types of hydrolyzed collagen serve as the backbone of Joint Vibrance. Human clinical trials have shown that new cartilage could be detected by x-ray examination of joints after six weeks of consuming 7 to 10 grams of type 1 collagen, or just 1 to 2 grams of type 2 collagen. Joint Vibrance supplies both type 2 and type 1 collagen.

Cartilage is made up of a mass of collagen fibers held together in a proteoglycan matrix or glue. (That glue is primarily synthesized from chondroitin sulfate A.) The collagen in cartilage – type 2 collagen – is slightly different in its composition than type 1 collagen found in bone, skin, tendons, blood vessel walls, and organs. As a result, supplemental type 2 collagen directly benefits cartilage synthesis.

Type 1 collagen aids the synthesis of cartilage when large doses are given, supports the integrity of tendons, and supports bone health. Bone is composed of 30% to 36% type 1 collagen. Since cartilage deterioration is often accompanied by bone deterioration, the type I collagen in Joint Vibrance will help maintain the integrity not only of cartilage, but also of bone and the stabilizing of tendons wrapped around joints. Joint Vibrance then, does not just seek to build cartilage, but expands beyond that role to improve all components of the joint.



CSA, Glucosamine & Hyaluronic acid

Chondroitin sulfate A is fashioned by chondrocytes into the sticky protein-sugar (proteoglycan) matrix, or glue, that holds all the collagen fibers together to form cartilage. Glucosamine is converted to hyaluronic acid by chondrocytes. Each molecule of hyaluronic acid contains 5 molecules of water, giving it a very large, slippery structure. Its goal is to escape the chondrocyte where it was made, and slowly work its way out through the cartilage to take its place as a major structural component in synovial fluid. Along the way, the glucosamine that has now become hyaluronic acid, rehydrates cartilage, giving it greater cushioning power. In addition, Joint Vibrance delivers 120mg of hyaluronic acid. This is intended to support and replenish the hyaluronic acid content of synovial fluids in every joint. But it takes more than collagen hydrolysates, glucosamine, chondroitin and hyaluronic acid to provide first class nutritional support to chondrocytes.

Silica/Silicon

Silica from horsetail contributes the element silicon to connective tissue, giving them strength and stability. It is found in precisely the tissues we are discussing here: bone, cartilage, and tendons (as well as skin and blood vessels) helping to make them strong.

Antioxidants

Inflammation in sore, aching joints is characterized by oxidative damage to cells in the affected area. White blood cells (leukocytes) and macrophages, immune cells that travel through tissues looking for damage to clean up, utilize free radicals to dismantle the cellular debris they ingest as part of their cleanup work. Free radicals, inadvertently released during the process, run amok, inflicting some damage to healthy tissue surrounding the original site of injury. Antioxidants can help control these biochemical events.

Grape seed extract, CurcuWIN™, ApresFlex® Boswellia serrata extract and bromelain extracted from pineapple stems all help quell free radical activity and resultant discomfort. Condensed tannins from grapeseed extract temporarily bind broken collagen fibers for a "quick fix" in connective tissues (e.g. ligaments, tendons, skin etc.). 1000 mg of MSM (methylsulfonyl methane) support flexible disulfide bonds in those same connective tissues.

ApresFlex® concentrates AKBA, the acronym for 3-O-Acetyl-11-keto-beta-boswellic acid. AKBA is the most active compound of Boswellia serrata extracts. AKBA is a potent inhibitor of the enzyme, 5-lipoxygenase (5-LOX), a key enzyme in the synthesis of cell messengers (leukotrienes) that are made from the ubiquitous omega-6 fatty acid, arachidonic acid. The dose of ApresFlex® required to quell the manufacture of leukotrienes is just 100 mg. That is what you will find in each serving of Joint Vibrance.*

