CV 16 - 00271

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

FEUERSTEIN, J.

SHIELDS, M.J.

KANEKA CORPORATION,

Plaintiff,

-against-

PIPING ROCK HEALTH PRODUCTS, LLC,

Defendant.

Civil Case No.

JURY TRIAL DEMANDED

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U.S. DISTRICT COURT
EASTERN DISTRICT
OF NEW YORK

COMPLAINT

Kaneka Corporation ("Kaneka"), for its Complaint against Piping Rock Health Products, LLC ("Piping Rock" or "Defendant"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for the infringement of United States Patent No. 7,829,080 (the "'080 Patent") under the Patent Laws of the United States, 35 U.S.C. §1 et seq. This action relates to Defendant's importation into the United States, and sales in the United States, of one or more products that infringe one or more claims of the '080 Patent.

THE PARTIES

2. Plaintiff Kaneka Corporation is a Japanese corporation with its principal place of business at 2-3-18, Nakanoshima, Kita-ku, Osaka 530-8288, Japan.

3. Kaneka has obtained patents issued by the United States Patent and Trademark Office for, among other things, Kaneka's innovative methods for manufacturing dietary and nutritional supplements. Kaneka owns and holds over 30 United States patents covering the manufacturing process for the nutritional supplement ubiquinol (reduced coenzyme Q_{10}), including U.S. Patent No. 7,829,080 (Exhibit A), as well as United States Patents covering the manufacturing process for the nutritional supplement ubiquinone (oxidized coenzyme Q_{10}).

4. Kaneka is the sole manufacturer in the United States under its patents for both ubiquinol and ubiquinone. Kaneka makes both of those products at its production plant in Pasadena, Texas.

5. Kaneka sells bulk Kaneka Ubiquinol™ to customers in the United States. The customers then produce finished products as nutritional supplements for sale online and at physical retail locations, such as GNC, Whole Foods, Target, CVS, and Walgreens, among others.

6. Upon information and belief, Defendant Piping Rock Health Products, LLC is a New York limited liability company with an office and its principal place of business at 2120 Smithtown Avenue, Ronkonkoma, NY 11779. Piping Rock markets and sells dietary and nutritional health supplements.

7. Mr. Scott Rudolph is the Defendant's co-founder and CEO. Previously, Mr. Rudolph was the CEO and Chairman of the Board of NBTY, another company that sells dietary and nutritional supplements. Mr. Rudolph sold NBTY in 2011 to a new owner who

retained the name NBTY. Mr. Rudolph then left NBTY and organized Defendant Piping Rock. Piping Rock hired and employs numerous former employees of NBTY.

8. Kaneka was selling Kaneka Ubiquinol™ to NBTY since 2007, both during the time and after Mr. Rudolph was CEO of NBTY. From the time of Kaneka's first sale of Kaneka Ubiquinol™ to NBTY, Kaneka informed NBTY, including Mr. Rudolph, that Kaneka owned numerous United States patents covering the production of ubiquinol, including the '080 patent. Kaneka similarly informed NBTY that Kaneka held United States patents covering the manufacture of ubiquinone. Upon information and belief, Mr. Rudolph and other employees at Defendant Piping Rock were likewise informed and knew that Kaneka had patents that covered both ubiquinol and ubiquinone. In addition, Kaneka has routinely informed the public of Kaneka's patents covering ubiquinol. *See* Exhibits, B, C and D.

9. Upon information and belief, Defendant Piping Rock had begun selling infringing ubiquinol as early as June 2015. For a limited period of time after Mr. Rudolph had left NBTY and had organized Defendant Piping Rock, NBTY was selling to Piping Rock Kaneka Ubiquinol™, either in the form of bulk product or finished products incorporating the bulk product. Kaneka was unaware of the arrangement between NBTY and Piping Rock until NBTY brought it to Kaneka's attention. In or about June 2015, Kaneka noticed that Piping Rock was not using Kaneka's trademark logo on its ubiquinol products. In response to Kaneka's inquiry, Piping Rock replied that it was not using Kaneka's trademark because it was no longer using Kaneka Ubiquinol™.

10. In an email dated June 23, 2015, Kaneka's National Sales Manager, Terese Mansell, notified and reminded Defendant's Director of Purchasing, Susan Stern, that Kaneka was the patent holder and sole manufacturer in the United States of Kaneka Ubiquinol™, and that Defendant could be infringing one or more of Kaneka's ubiquinol patents by selling ubiquinol not made by Kaneka.

11. Defendant Piping Rock denied infringement, disingenuously stating it did not infringe one of Kaneka's ubiquinone patents by selling ubiquinol, thereby attempting to deflect Kaneka's inquiry and its notice to Defendant of its infringement and to deny Piping Rock's knowledge of Kaneka's ubiquinol patents.

12. Kaneka then conducted tests on Defendant Piping Rock's 100mg Ubiquinol/Softgel product to determine whether Defendant infringed one or more claims of the '080 patent. The tests conducted by Kaneka showed that the 100mg Ubiquinol/Softgel Piping Rock product infringes at least claims 1, 5, 14 and 15 of the '080 patent, and upon information and belief, all other ubiquinol products being sold by Defendant also infringe claims 1, 5, 14 and 15 of the '080 patent.

JURISDICTION AND VENUE

13. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

14. This Court has personal jurisdiction over Defendant because Defendant's principal place of business is located in the State of New York and within the Eastern District

of New York. Personal jurisdiction also exists specifically over Defendant because it makes, uses, offers for sale, sells, imports, advertises, makes available and/or markets one or more products within the State of New York, and more particularly, within the Eastern District of New York, and has purposely availed itself of the privileges and benefits of the laws of the State of New York.

15. Upon information and belief, Defendant, directly and/or through intermediaries, imports, ships, distributes, offers for sale, sells, and/or advertises infringing ubiquinol products in the United States and the State of New York.

16. Upon information and belief, Defendant has committed patent infringement in the State of New York. Defendant solicits customers in the State of New York. Upon information and belief, Defendant has paying customers who are residents of the State of New York and who use Defendant's products in the State of New York.

17. Venue is proper in this judicial district as to Defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b) because Defendant has committed acts of infringement in the Eastern District of New York and has transacted business in the Eastern District of New York.

THE PATENT-IN SUIT

18. Paragraphs 1-15 are incorporated by reference as if fully set forth herein.

19. On November 9, 2010, the '080 Patent entitled "Stabilization Method Of Reduced Coenzyme Q_{10}" was duly and lawfully issued to Kaneka by the United States Patent and Trademark Office ("PTO"). Kaneka owns the '080 Patent.

COUNT I – PATENT INFRINGEMENT

20. Paragraphs 1-17 are incorporated by reference as if fully restated herein.

21. Prior to the filing of this Complaint, Kaneka conducted tests on Defendant Piping Rock's 100mg Ubiquinol/Softgel product to determine whether Defendant infringed one or more claims of the '080 patent. The tests conducted by Kaneka showed that the 100mg Ubiquinol/Softgel Piping Rock product infringes at least claims 1, 5, 14 and 15 of the '080 patent, and upon information and belief, all other ubiquinol products being sold by Defendant also infringe claims 1, 5, 14 and 15 of the '080 patent.

22. Accordingly, upon information and belief, Defendant, in violation of 35 U.S.C. § 271, has directly and indirectly, literally or under the doctrine of equivalents, through inducement and contribution, infringed and continues to infringe at least one or more claims of the '080 Patent by making, using, importing, providing, offering to sell, and selling (directly or through intermediaries), in this District and elsewhere in the United States, its ubiquinol nutritional and dietary supplements.

23. To the extent notice may be required, Defendant received actual notice of its infringement of the '080 Patent upon the filing of the Complaint in this action. Defendant also received written notice as early as June, 2015 from Kaneka that Defendant was infringing Kaneka's ubiquinol patents by selling ubiquinol products obtained from a source other than Kaneka.

24. Upon information and belief, Defendant's aforesaid activities have been willful, deliberate and intentional, without authority and/or license from Kaneka. Defendant's

intentional infringing activity has continued with knowledge of Kaneka's Ubiquinol patents, including the '080 patent, thereby acting to infringe despite an objectively high likelihood that its actions constituted infringement of a valid patent, and attempting to covertly act and acting in reckless disregard of Kaneka's patent rights.

25. Kaneka is entitled to recover from Defendant the damages sustained by Kaneka as a result of the Defendant's wrongful acts in an amount subject to proof at trial, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284, as well as a trebling of damages due to Defendant's willful infringement.

26. Defendant's infringement of Kaneka's ownership and exclusive rights under the '080 Patent will continue to damage Kaneka, causing irreparable harm for which there is no adequate remedy at law, unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court order and direct entry of judgment against Defendant as follows:

A. declaring that Defendant has infringed the '080 Patent;

B. declaring that Defendant be and is preliminarily and/or permanently enjoined from engaging in further infringement;

C. awarding to Plaintiff damages to be paid by Defendant adequate to compensate Plaintiff for its past infringement and any continuing or future infringement

up until the date such judgment is entered, including statutory interest, costs, and disbursements as justified under 35 U.S.C. § 284 and, if necessary to adequately compensate Plaintiff for Defendant's infringement, an accounting of all infringing sales, including, but not limited to, those sales not presented at trial;

D. declaring that Defendant's infringement has been willful, justifying a trebling of the award of damages under 35 U.S.C. § 284, or such other enhancement of the award of damages that the Court deems appropriate;

E. declaring that this case is exceptional under 35 U.S.C. § 285;

F. awarding to Plaintiff its attorney fees, costs, and expenses incurred in prosecuting this action; and

G. awarding to Plaintiff such further relief at law or in equity as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all claims and issues so triable.

Dated: January 19, 2016

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EXHIBIT A

(12) **United States Patent**
Ueda et al.

(10) **Patent No.: US 7,829,080 B2**
(45) **Date of Patent: Nov. 9, 2010**

(54) **STABILIZATION METHOD OF REDUCED COENZYME Q_{10}**

(75) Inventors: **Takahiro Ueda**, Kobe (JP); **Shiro Kitamura**, Akashi (JP); **Hiroshi Kubo**, Kobe (JP); **Kazunori Hosoe**, Takasago (JP)

(73) Assignee: **Kaneka Corporation**, Osaka-shi (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **11/741,290**

(22) Filed: **Apr. 27, 2007**

(65) **Prior Publication Data**

US 2007/0258966 A1 Nov. 8, 2007

(30) **Foreign Application Priority Data**

Apr. 28, 2006 (JP) 2006-126897

(51) **Int. Cl.**
A61K 9/64 (2006.01)
A61K 38/43 (2006.01)
A61K 38/54 (2006.01)

(52) **U.S. Cl.** **424/94.1**; 424/451; 424/455; 424/456

(58) **Field of Classification Search** ..... None
See application file for complete search history.

(56) **References Cited**

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Lekli et al. (2008) J. Agric. Food chem. 56: 5331-5337.*
Selvam et al., *Nutrition Research*, 13: 667-676 (1993).
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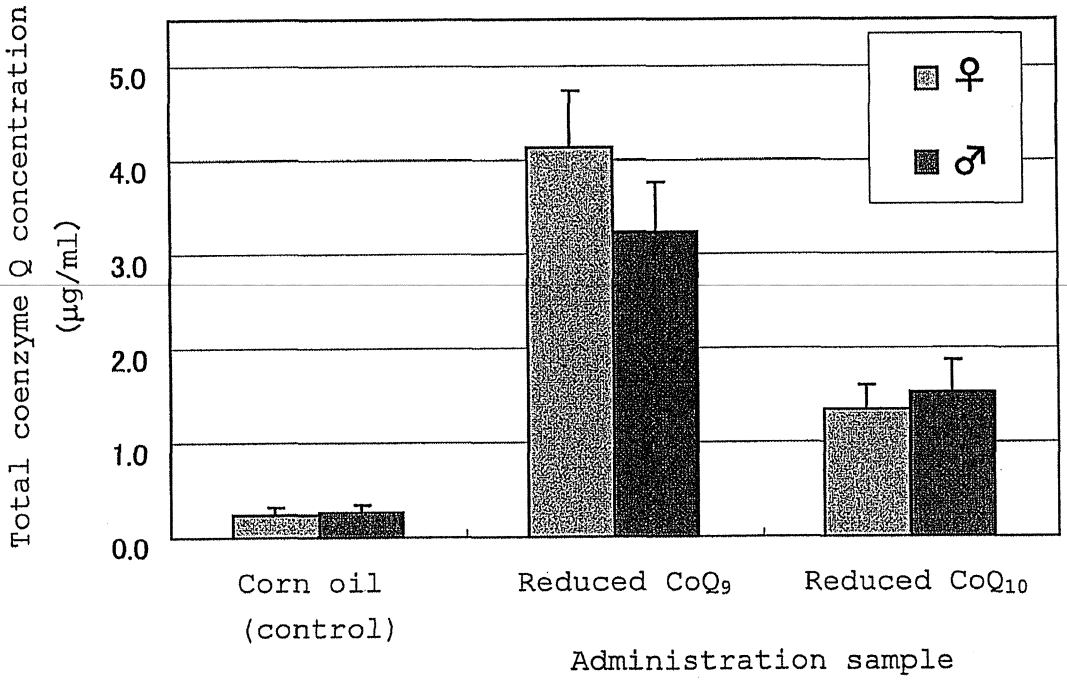
Primary Examiner—Lisa J Hobbs
(74) *Attorney, Agent, or Firm*—Leydig, Voit & Mayer, Ltd.

(57) **ABSTRACT**

The present invention provides a method for stabilizing reduced coenzyme Q_{10}, which is useful as a food, nutritional product, nutritional supplement, animal drug, drink, feed, cosmetic, pharmaceutical product, therapeutic drug, prophylactic drug and the like. The present invention also provides a method of producing a reduced coenzyme Q_{10}-containing composition which includes the co-presence of reduced coenzyme Q_{10} and reduced coenzyme Q_9 and/or reduced coenzyme Q_{11}.

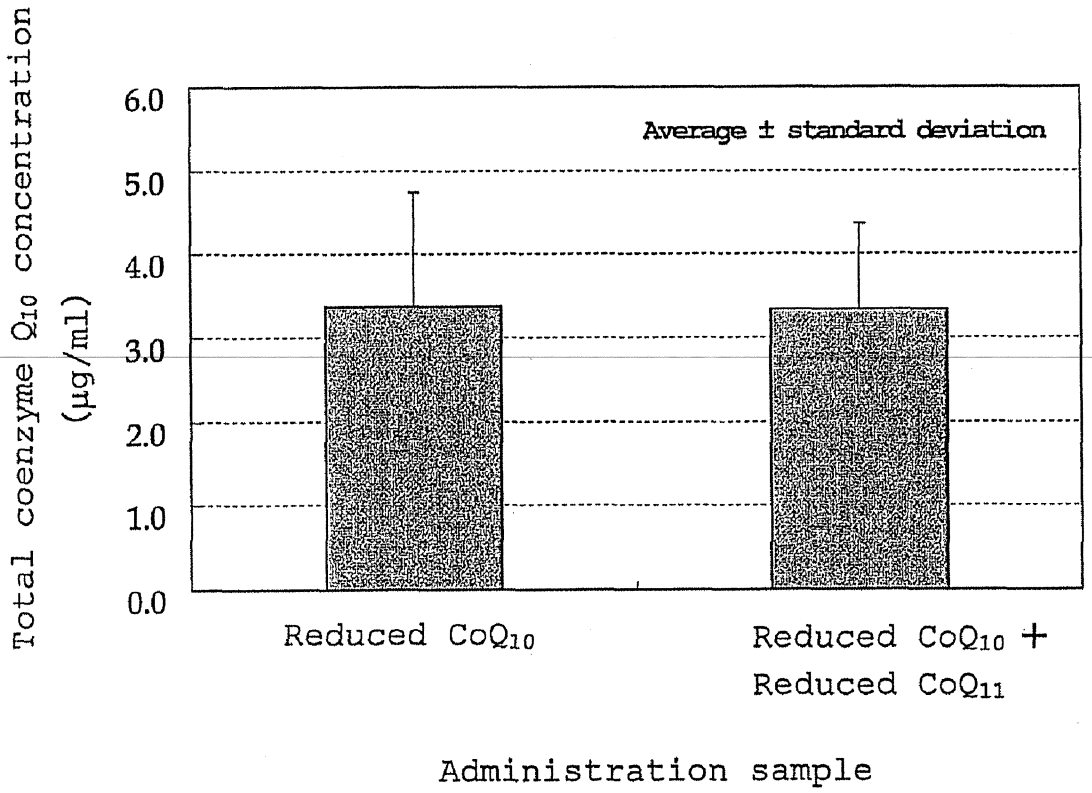
18 Claims, 2 Drawing Sheets

Fig. 1



Total coenzyme Q in rat plasma

Fig. 2



Total coenzyme Q_{10} in rat plasma

STABILIZATION METHOD OF REDUCED COENZYME Q_{10}

BACKGROUND OF THE INVENTION

It is known that reduced coenzyme Q_{10} can be obtained, for example, by a method comprising producing coenzyme Q_{10} by a conventionally known method such as synthesis, fermentation, extraction from a naturally occurring substance and the like, and concentrating a reduced coenzyme Q_{10} fraction in an eluate from chromatography and the like (see JP-A-10-109933). In this case, oxidized coenzyme Q_{10} contained in the above-mentioned reduced coenzyme Q_{10} can be reduced with a general reducing agent such as sodium borohydride, sodium dithionite (sodium hydrosulfite) and the like, and concentrated by chromatography, and that the reduced coenzyme Q_{10} can also be obtained by a method comprising reacting existing highly pure coenzyme Q_{10} with the above-mentioned reducing agent.

In addition, production methods for conveniently obtaining reduced coenzyme Q_{10} are also disclosed (e.g., WO 03/06408, WO 03/06409 and WO 03/32967).

However, reduced coenzyme Q_{10} is easily oxidized by molecular oxygen into oxidized coenzyme Q_{10}, and therefore, stabilization of reduced coenzyme Q_{10} is an important issue when it is processed into a food, food with nutrient function claims, food for specified health use, nutritional product, nutritional supplement, animal drug, drink, feed, pet food, cosmetic, pharmaceutical product, therapeutic drug, prophylactic drug and the like, or a material or composition therefor, or preserved after processing and the like. Complete removal or blocking of oxygen during the above-mentioned processing and preservation is extremely difficult, and remaining or admixed oxygen particularly during heating for processing and long-term preservation exerts a markedly adverse effect. The above-mentioned oxidation is directly related to quality problems such as the by-product oxidized coenzyme Q_{10}.

As mentioned above, stabilization of reduced coenzyme Q_{10} (protection of oxidation) is a highly important object. However, since reduced coenzyme Q_{10} is not commercially available to date, the study of methods and compositions for stable retention of reduced coenzyme Q_{10} has not been undertaken very much.

As a conventionally-known method for stably retaining reduced coenzyme Q_{10}, a method including addition of a reducing agent is known. However, some of the reducing agents used therefor are not suitable for food and pharmaceutical agents. For example, WO 01/52822, which discloses a composition concurrently containing a reducing agent and a production method thereof, also discloses (1) a composition comprising reduced coenzyme Q_{10}; a reducing agent in an amount effective for eliminating oxidation of reduced coenzyme Q_{10} into oxidized coenzyme Q_{10}; a surfactant, vegetable oil or a mixture thereof in an amount effective for dissolving the above-mentioned reduced coenzyme Q_{10} and the above-mentioned reducing agent; and a solvent as necessary, (2) a composition for oral administration wherein the above-mentioned composition is prepared into a gelatin capsule or a tablet, and (3) a method of preparing the above-mentioned composition containing reduced coenzyme Q_{10} in situ using oxidized coenzyme Q_{10} and a reducing agent. However, no detailed description relating to the quality, stabilizing effect and the like of the reduced coenzyme Q_{10} contained in the composition is provided, and the expected level of stabilization is not clear.

In addition, the above-mentioned composition and preparation method thereof are highly complicated and complex since plural roles are conferred to the composition (i.e., firstly, a role as a reaction site for reducing oxidized coenzyme Q_{10} to reduced coenzyme Q_{10}, and secondly, a role of stably retaining reduced coenzyme Q_{10}). Moreover, the above-mentioned composition and a preparation method thereof are not entirely safe because the reaction mixture is used as it is. In other words, ascorbic acids to be used as reducing agents are oxidized to produce a considerable amount of dehydroascorbic acids, and the dehydroascorbic acids get mixed in with the above-mentioned composition, posing a problem. Dehydroascorbic acids and oxalic acid produced by decomposition from dehydroascorbic acids are highly noxious, unlike ascorbic acids. For example, an increased amount of lipid peroxide and a decreased amount of antioxidants in the liver and kidney, and an increased amount of oxalic acid in the kidney have been reported, and side effects such as decreased resistance to oxidation stress, easy onset of ureteral lithiasis (Nutrition Research Vol. 13, page 667-676, 1993) and the like are feared.

SUMMARY OF THE INVENTION

The present invention aims at providing a convenient and preferable method and a composition for stably retaining reduced coenzyme Q_{10} by protection against oxidation while maintaining high safety, during processing into a food, food with nutrient function claims, food for specified health use, nutritional product, nutritional supplement, animal drug, drink, feed, pet food, cosmetic, pharmaceutical product, therapeutic drug, prophylactic drug containing reduced coenzyme Q_{10} and the like, or a material or composition therefor, and/or preservation after processing and the like.

The present inventors have conducted intensive studies in an attempt to solve the above-mentioned problems and found that reduced coenzyme Q_{10} can be stabilized by the co-presence of reduced coenzyme Q_9 and/or reduced coenzyme Q_{11}, which are analogs of reduced coenzyme Q_{10}.

That is, they have found that reduced coenzyme Q_{10} can be stably retained by protecting the reduced coenzyme Q_{10} from oxidation by the co-presence of reduced coenzyme Q_9 (not less than 0.6 wt % relative to reduced coenzyme Q_{10}) and/or reduced coenzyme Q_{11}, even when a reducing agent is not used as a necessary component to be added, which resulted in the completion of the present invention.

Accordingly, the present invention provides the following embodiments.

[1] A method for stabilizing reduced coenzyme Q_{10}, which method comprises preparing a reduced coenzyme Q_{10}-containing composition comprising reduced coenzyme Q_{10} and one or both of (a) and (b):

(a) not less than 0.6 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}, and

(b) reduced coenzyme Q_{11},

thereby stabilizing reduced coenzyme Q_{10}.

[2] The method of [1], wherein the amount of the reduced coenzyme Q_9 is not less than 1 wt % relative to reduced coenzyme Q_{10}.

[3] The method of [1], wherein the reduced coenzyme Q_{10}-containing composition comprises not less than 0.6 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}.

[4] The method of [1]-[3], wherein the method comprises

preparing one or both of (a) the reduced coenzyme Q_9 and (b) the reduced coenzyme Q_{11}, and then

adding one or both of (a) the reduced coenzyme Q_9 and (b) the reduced coenzyme Q_{11} to the reduced coenzyme Q_{10} to prepare the reduced coenzyme Q_{10}-containing composition.

[5] The method of [1]-[3], wherein the method comprises

providing a composition comprising oxidized coenzyme Q_{10} and one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11}, and then

reducing oxidized coenzyme Q_{10} and reducing one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11} to prepare the reduced coenzyme Q_{10}-containing composition.

[6] The method of [1]-[5], wherein the reduced coenzyme Q_{10}-containing composition is prepared under a deoxygenation atmosphere.

[7] A reduced coenzyme Q_{10}-containing composition comprising reduced coenzyme Q_{10} and one or both of (a) and (b):

(a) not less than 0.6 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}, and

(b) reduced coenzyme Q_{11}.

[8] The composition of [7], wherein the amount of the reduced coenzyme Q_9 is not less than 1 wt % relative to reduced coenzyme Q_{10}.

[9] The composition of [7], wherein the composition comprises not less than 0.6 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}.

[10] The composition of [7]-[9], wherein the reduced coenzyme Q_{10} is in crystalline form.

[11] The composition of [7]-[9], wherein the reduced coenzyme Q_{10} is dissolved or suspended in a solvent.

[12] The composition of [7]-[9], wherein the reduced coenzyme Q_{10} is a melt.

[13] The composition of [7]-[12], which further comprises a pharmaceutically acceptable carrier.

[14] The composition of [7]-[13], which is in a form suitable for administration to a mammal and comprises reduced coenzyme Q_{10} as an active ingredient.

[15] The composition of [7]-[14], which further comprises at least one component selected from the group consisting of an excipient, a disintegrant, a lubricant, a binder, an antioxidant, a coloring agent, an anticoagulant, an absorption promoter, a solubilizing agent for the active ingredient, a stabilizer, an active ingredient other than reduced coenzyme Q_{10}, and combinations thereof.

[16] An oral dosage form comprising the composition of [15], which dosage form is a capsule.

[17] The oral dosage form of [16], wherein the capsule is a microcapsule, a soft capsule, or a hard capsule.

[18] A method for producing a reduced coenzyme Q_{10}-containing composition, which method comprises

preparing one or both of (a) reduced coenzyme Q_9 and (b) reduced coenzyme Q_{11}, and then

adding one or both of (a) the reduced coenzyme Q_9 and (b) the reduced coenzyme Q_{11} to reduced coenzyme Q_{10} to prepare the reduced coenzyme Q_{10}-containing composition,

wherein the composition comprises reduced coenzyme Q_{10} and one or both of (a) not less than 0.6 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10} and (b) reduced coenzyme Q_{11}.

[19] The method of [18], wherein the reduced coenzyme Q_{10}-containing composition comprises not less than 0.6 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}.

[20] A method for producing a reduced coenzyme Q_{10}-containing composition, which method comprises

providing a composition comprising oxidized coenzyme Q_{10} with one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11}, and then

reducing oxidized coenzyme Q_{10} and reducing one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11} to prepare the reduced coenzyme Q_{10}-containing composition,

wherein the composition comprises reduced coenzyme Q_{10} and one or both of (a) not less than 0.6 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10} and (b) reduced coenzyme Q_{11}.

[21] The method of [20], wherein the reduced coenzyme Q_{10}-containing composition comprises not less than 0.6 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a bar graph that sets forth the concentration of the total coenzyme Q (μg/ml) in plasma from male and female rats following administration of (1) corn oil (control), (2) reduced coenzyme Q_9, and (3) reduced coenzyme Q_{10} as set forth in Example 3.

FIG. **2** is a bar graph that sets forth the concentration of the total coenzyme Q (μg/ml) in plasma from male rats following the administration of (1) reduced coenzyme Q_{10} or (2) a reduced coenzyme Q_{10} and reduced coenzyme Q_{11} mixture as set forth in Example 4.

DETAILED DESCRIPTION OF THE INVENTION

According to the present invention, a stabilization method of reduced coenzyme Q_{10} can be provided by a mere co-presence of an analog of reduced coenzyme Q_{10} even when multiple components, particularly a reducing agent, are not used as necessary components to protect the reduced coenzyme Q_{10} from oxidation. Therefore, highly safe reduced coenzyme Q_{10} can be provided, which is free of a noxious substance such as dehydroascorbic acid, oxalic acid and the like produced when ascorbic acid and the like is used as a reducing agent.

Moreover, reduced coenzyme Q_9 and reduced coenzyme Q_{11} show the same effect in the body as reduced coenzyme Q_{10}. Therefore, when reduced coenzyme Q_9 and reduced coenzyme Q_{11} contained in reduced coenzyme Q_{10} are ingested, the effect of the reduced coenzyme Q_{10} is not prevented, and a greater effect of coenzyme Q can be exhibited as compared to a composition containing reduced coenzyme Q_{10} alone, and the like. Furthermore, since the absorbability of reduced coenzyme Q_9 in the body is greater than that of reduced coenzyme Q_{10}, a composition containing reduced coenzyme Q_9 and reduced coenzyme Q_{10} in combination shows higher absorbability in terms of the total amount of coenzyme Q.

The present invention is explained in detail below. In the present specification, the phrase "coenzyme Q_{10}," when simply expressed includes the oxidized form, the reduced form, and/or a mixture thereof when they are both present.

In the present invention, reduced coenzyme Q_{10} can contain oxidized coenzyme Q_{10}. When oxidized coenzyme Q_{10} is also present, the proportion of reduced coenzyme Q_{10} in the total amount of coenzyme Q_{10} (i.e., the total amount of reduced coenzyme Q_{10} and oxidized coenzyme Q_{10}) is not

particularly limited. Preferably, the proportion of reduced coenzyme Q_{10} in the total amount of coenzyme Q_{10} is not less than 20 wt % (e.g., not less than 25 wt %, not less than 30 wt %, not less than 35 wt %, not less than 40 wt %, not less than 45 wt %, not less than 50 wt %, not less than 60 wt %, not less than 65 wt %, not less than 70 wt %, not less than 75 wt %, not less than 80 wt %, not less than 85 wt %, not less than 90%, not less than 95%, or not less than 96%). While the upper limit is not particularly limited (i.e., the upper limit can be 100 wt %), typically the upper limit is not more than 99.9 wt % (e.g., not more than 99.5 wt %, or not more than 99.0 wt %).

Reduced coenzyme Q_{10} can be obtained by various methods as mentioned above. For example, reduced coenzyme Q_{10} having a high proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} can be efficiently obtained by the method described in WO 03/06408.

The stabilization method of the reduced coenzyme Q_{10} of the present invention (hereinafter to be also referred to as the stabilization method of the present invention) is a method characterized by the co-presence of (a) not less than 0.6 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}, and/or (b) reduced coenzyme Q_{11}, which suppresses oxidation of reduced coenzyme Q_{10} into oxidized coenzyme Q_{10} by molecular oxygen, and stably retains the reduced coenzyme Q_{10}.

While the amount of reduced coenzyme Q_9 and/or reduced coenzyme Q_{11} contained in reduced coenzyme Q_{10} is not particularly limited, the amount of the reduced coenzyme Q_9 is generally not less than about 0.6 wt %, preferably not less than about 1 wt %, more preferably not less than about 1.5 wt %, more preferably not less than about 2 wt %, and most preferably not less than about 3 wt %, relative to reduced coenzyme Q_{10}.

The amount of reduced coenzyme Q_{11} is generally not less than about 0.1 wt %, preferably not less than about 0.5 wt %, and more preferably not less than about 1 wt %, relative to reduced coenzyme Q_{10}.

While the upper limit of reduced coenzyme Q_9 and/or reduced coenzyme Q_{11} contained in reduced coenzyme Q_{10} is not particularly limited, it is generally not more than about 99 wt % (e.g., not more than about 90 wt %, not more than about 80 wt %, not more than about 70 wt %, not more than about 60 wt %, not more than about 50 wt %, or not more than about 40 wt %). Both reduced coenzyme Q_9 and reduced coenzyme Q_{10} can be present with reduced coenzyme Q_{10}.

In the stabilization method of the present invention, the aforementioned (a) and/or (b) can be separately prepared by any suitable technique. For example, the separate preparation can be preparation by extraction and purification from a naturally occurring substance, reduction of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11} according to the aforementioned method described in WO 03/06408, or coupling reaction of isoprenyl side chain with 2-methyl-5,6-dimethoxy-1, 4-benzohydroquinone and the like. The reduced coenzyme Q_{10} can also be stabilized by adding (a) and/or (b) obtained by such preparation to reduced coenzyme Q_{10}.

The stabilization method of the present invention also includes the co-presence of reduced coenzyme Q_{10} and (a) and/or (b) by the reduction of oxidized coenzyme Q_{10} containing oxidized coenzyme Q_9 and/or oxidized coenzyme Q_{11}.

The method of reducing oxidized coenzyme Q_{10} containing oxidized coenzyme Q_9 and/or oxidized coenzyme Q_{11} can be performed according to the method described in WO 03/06408 and the like.

The reduced coenzyme Q_{10}-containing composition of the present invention (hereinafter to be also referred to as the composition of the present invention) is a composition characterized by the co-presence of (a) not less than 0.6 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}, and/or (b) reduced coenzyme Q_{11}.

Preferable amounts of reduced coenzyme Q_9 and/or reduced coenzyme Q_{11} to be contained in reduced coenzyme Q_{10} are as mentioned above.

The composition of the present invention can be obtained by adding separately prepared reduced coenzyme Q_9 and/or reduced coenzyme Q_{11} to reduced coenzyme Q_{10}, or reducing oxidized coenzyme Q_{10} containing oxidized coenzyme Q_9 and/or oxidized coenzyme Q_{11}.

The production method of the reduced coenzyme Q_{10}-containing composition of the present invention (hereinafter to be also referred to as the production method of the present invention) is a production method of a reduced coenzyme Q_{10}-containing composition comprising the aforementioned (a) and/or (b) in combination, which includes separately preparing and adding (a) and/or (b).

The production method of reduced coenzyme Q_{10} containing reduced coenzyme Q_9 and/or reduced coenzyme Q_{11} is not particularly limited. The step of separately preparing and adding (a) and/or (b) can be a step for adding (a) and/or (b) separately prepared as mentioned above. The preparation and addition can be performed by any suitable method known in the art.

The production method of the present invention includes a step of reducing oxidized coenzyme Q_{10} containing of oxidized coenzyme Q_9 (not less than 0.6 wt % relative to oxidized coenzyme Q_{10}) and/or oxidized coenzyme Q_{11}. By this step, reduced coenzyme Q_{10}-containing composition containing (a) and/or (b) in combination (and in the previously mentioned amounts) can be finally obtained.

The method (step) of reducing oxidized coenzyme Q_{10} containing oxidized coenzyme Q_9 and/or oxidized coenzyme Q_{11}, and the method (step) of adding reduced coenzyme Q_9 and/or reduced coenzyme Q_{11} prepared separately, can be employed in combination.

The form of the reduced coenzyme Q_{10}-containing composition containing reduced coenzyme Q_9 and/or reduced coenzyme Q_{11} in combination of the present invention is not particularly limited, and can be a crystal; dissolved or suspended in a solvent; a melt maintained at not less than the melting point; or in a form for administration to mammals such as an agent for oral administration, external preparation and the like.

In the present invention, the form of contact between reduced coenzyme Q_{10} and reduced coenzyme Q_9 and/or reduced coenzyme Q_{11} is not particularly limited. For example, reduced coenzyme Q_{10} and reduced coenzyme Q_9 and/or reduced coenzyme Q_{11} can be present as crystals, or dissolved and/or suspended in any solvent. Also, reduced coenzyme Q_9 and/or reduced coenzyme Q_{11} can be dissolved in a melted solution of reduced coenzyme Q_{10}.

As the solvent usable in the present invention is not particularly limited, and hydrocarbons, fatty acid esters, ethers, alcohols, fatty acids, ketones, nitrogen compounds (including nitriles and amides), sulfur compounds, fats and oils, water and the like can be used. These solvents can be a mixture of any two or more kinds of solvents.

The suitable hydrocarbons are not particularly limited. For example, aliphatic hydrocarbon, aromatic hydrocarbon, halogenated hydrocarbon and the like can be used. Aliphatic hydrocarbon and aromatic hydrocarbon are preferable, and aliphatic hydrocarbon is especially preferable.

Aliphatic hydrocarbons can be cyclic or non-cyclic, saturated or unsaturated, and are not particularly limited. Generally, saturated aliphatic hydrocarbons are preferably used.

Aliphatic hydrocarbons having 3 to 20 carbon atoms, particularly 5 to 12 carbon atoms, especially 5 to 8 carbon atoms, are preferably used. Specific examples include propane, butane, isobutane, pentane, 2-methylbutane, hexane, 2-methylpentane, 2,2-dimethylbutane, 2,3-dimethylbutane, heptane, heptane isomer (e.g., 2-methylhexane, 3-methylhexane, 2,3-dimethylpentane, 2,4-dimethylpentane), octane, 2,2,3-trimethylpentane, isooctane, nonane, 2,2,5-trimethylhexane, decane, dodecane, 2-pentene, 1-hexene, 1-heptene, 1-octene, 1-nonene, 1-decene, cyclopentane, methylcyclopentane, cyclohexane, methylcyclohexane, ethylcyclohexane, p-menthane, cyclohexene and the like.

Of these, pentane, 2-methylbutane, hexane, 2-methylpentane, 2,2-dimethylbutane, 2,3-dimethylbutane, heptane, heptane isomer (e.g., 2-methylhexane, 3-methylhexane, 2,3-dimethylpentane, 2,4-dimethylpentane), octane, 2,2,3-trimethylpentane, isooctane, nonane, 2,2,5-trimethylhexane, decane, dodecane, cyclopentane, methylcyclopentane, cyclohexane, methylcyclohexane, ethylcyclohexane, p-menthane and the like are preferable, and particularly, pentane, 2-methylbutane, hexane, 2-methylpentane, 2,2-dimethylbutane, 2,3-dimethylbutane, heptane, heptane isomer (e.g., 2-methylhexane, 3-methylhexane, 2,3-dimethylpentane, 2,4-dimethylpentane), octane, 2,2,3-trimethylpentane, isooctane, cyclopentane, methylcyclopentane, cyclohexane, methylcyclohexane, ethylcyclohexane and the like are preferable.

Pentanes having 5 carbon atoms (e.g., pentane etc.), hexanes having 6 carbon atoms (e.g., hexane, cyclohexane etc.), heptanes having 7 carbon atoms (e.g., heptane, methylcyclohexane etc.) and the like, as well as mixtures thereof (e.g., two or more heptanes) are preferably used. Heptanes (e.g., heptane, methylcyclohexane etc.) are most preferable, and heptane is especially preferable.

While aromatic hydrocarbons are not particularly limited, normally, an aromatic hydrocarbon having 6 to 20 carbon atoms, particularly 6 to 12 carbon atoms, especially 7 to 10 carbon atoms, is preferably used. Specific examples include benzene, toluene, xylene, o-xylene, m-xylene, p-xylene, ethylbenzene, cumene, mesitylene, tetralin, butylbenzene, p-cymene, cyclohexylbenzene, diethylbenzene, pentylbenzene, dipentylbenzene, dodecylbenzene, styrene and the like.

Of these, toluene, xylene, o-xylene, m-xylene, p-xylene, ethylbenzene, cumene, mesitylene, tetralin, butylbenzene, p-cymene, cyclohexylbenzene, diethylbenzene, pentylbenzene and the like are preferable, and particularly, toluene, xylene, o-xylene, m-xylene, p-xylene, cumene, tetralin and the like are preferable. Cumene is most preferable.

Halogenated hydrocarbons can be cyclic or non-cyclic, saturated or unsaturated, and are not particularly limited. In general, a non-cyclic halogenated hydrocarbon is preferably used. Halogenated hydrocarbon having 1 to 6 carbon atoms, particularly 1 to 4 carbon atoms, especially 1 or 2 carbon atoms, are preferably used. Chlorinated hydrocarbon and fluorinated hydrocarbon are preferable, and chlorinated hydrocarbon is particularly preferable. Specific examples include dichloromethane, chloroform, carbon tetrachloride, 1,1-dichloroethane, 1,2-dichloroethane, 1,1,1-trichloroethane, 1,1,2-trichloroethane, 1,1,1,2-tetrachloroethane, 1,1,2,2-tetrachloroethane, pentachloroethane, hexachloroethane, 1,1-dichloroethylene, 1,2-dichloroethylene, trichloroethylene, tetrachloroethylene, 1,2-dichloropropane, 1,2,3-trichloropropane, chlorobenzene, 1,1,1,2-tetrafluoroethane and the like.

Of these, dichloromethane, chloroform, carbon tetrachloride, 1,1-dichloroethane, 1,2-dichloroethane, 1,1,1-trichloroethane, 1,1,2-trichloroethane, 1,1-dichloroethylene, 1,2-dichloroethylene, trichloroethylene, chlorobenzene, 1,1,1,2-tetrafluoroethane and the like preferably, particularly, dichloromethane, chloroform, 1,2-dichloroethylene, trichloroethylene, chlorobenzene, 1,1,1,2-tetrafluoroethane and the like are preferable.

Fatty acid esters are not particularly limited. For example, propionic acid ester, acetic acid ester, formic acid ester and the like can be used. Acetic acid ester and formic acid ester are preferable, and acetic acid ester is particularly preferable.

While the ester group is not particularly limited, alkyl ester or aralkyl ester having 1 to 8 carbon atoms, preferably aralkyl ester having 1 to 6 carbon atoms, more preferably aralkyl ester having 1 to 4 carbon atoms is preferably used.

Specific examples of propionic acid ester include methyl propionate, ethyl propionate, butyl propionate and isopentyl propionate.

Specific examples of acetic acid ester include methyl acetate, ethyl acetate, propyl acetate, isopropyl acetate, butyl acetate, isobutyl acetate, sec-butyl acetate, pentyl acetate, isopentyl acetate, sec-hexyl acetate, cyclohexyl acetate, benzyl acetate and the like. Of these, methyl acetate, ethyl acetate, propyl acetate, isopropyl acetate, butyl acetate, isobutyl acetate, sec-butyl acetate, pentyl acetate, isopentyl acetate, sec-hexyl acetate, cyclohexyl acetate and the like are preferable. Methyl acetate, ethyl acetate, propyl acetate, isopropyl acetate, butyl acetate, isobutyl acetate and the like are more preferable, and ethyl acetate is particularly preferable.

Examples of formic acid ester include methyl formate, ethyl formate, propyl formate, isopropyl formate, butyl formate, isobutyl formate, sec-butyl formate, pentyl formate and the like.

Of these, methyl formate, ethyl formate, propyl formate, butyl formate, isobutyl formate, pentyl formate and the like are preferable. Ethyl formate is more preferable.

Ethers can be cyclic or non-cyclic, saturated or unsaturated, and are not particularly limited. In general, saturated ethers are preferably used.

Ether having 3 to 20 carbon atoms, particularly ether having 4 to 12 carbon atoms, especially ether having 4 to 8 carbon atoms, is preferably used. Specific examples include diethyl ether, methyl tert-butyl ether, dipropyl ether, diisopropyl ether, dibutyl ether, dihexyl ether, ethylvinyl ether, butylvinyl ether, anisole, phenetol, butylphenyl ether, methoxytoluene, dioxane, furan, 2-methylfuran, tetrahydrofuran, tetrahydropyran, ethylene glycol dimethyl ether, ethylene glycol diethyl ether, ethylene glycol dibutyl ether, ethylene glycol monomethyl ether, ethylene glycol monoethyl ether, ethylene glycol dibutyl ether and the like.

Of these, diethyl ether, methyl tert-butyl ether, dipropyl ether, diisopropyl ether, dibutyl ether, dihexyl ether, anisole, phenetol, butylphenyl ether, methoxytoluene, dioxane, 2-methylfuran, tetrahydrofuran, tetrahydropyran, ethylene glycol dimethyl ether, ethylene glycol diethyl ether, ethylene glycol dibutyl ether, ethylene glycol monomethyl ether, ethylene glycol monoethyl ether and the like are preferable, and particularly, diethyl ether, methyl tert-butyl ether, anisole, dioxane, tetrahydrofuran, ethylene glycol monomethyl ether, ethylene glycol monoethyl ether and the like are preferable.

Diethyl ether, methyl tert-butyl ether, anisole, dioxane, tetrahydrofuran and the like are most preferable, and dioxane and tetrahydrofuran are particularly preferable.

Nitriles can be cyclic or non-cyclic, saturated or unsaturated, and are not particularly limited. In general, saturated nitrites are preferably used.

A nitrile having 2 to 20 carbon atoms, particularly a nitrile having 2 to 12 carbon atoms, especially nitrile having 2 to 8 carbon atoms, is preferably used. Specific examples include acetonitrile, propionitrile, malononitrile, butyronitrile, isobutyronitrile, succinonitrile, valeronitrile, glutaronitrile, hexanenitrile, heptyl cyamide, octyl cyamide, undecanenitrile, dodecanenitrile, tridecanenitrile, pentadecanenitrile, stearonitrile, chloroacetonitrile, bromoacetonitrile, chloropropionitrile, bromopropionitrile, methoxyacetonitrile, methyl cyanoacetate, ethyl cyanoacetate, tolunitrile, benzonitrile, chlorobenzonitrile, bromobenzonitrile, cyanobenzoic acid, nitrobenzonitrile, anisonitrile, phthalonitrile, bromotolunitrile, methylcyanobenzoate, methoxybenzonitrile, acetylbenzonitrile, naphtonitrile, biphenylcarbonitrile, phenylpropionitrile, phenylbutyronitrile, methylphenylacetonitrile, diphenylacetonitrile, naphthylacetonitrile, nitrophenylacetonitrile, chlorobenzyl cyamide, cyclopropanecarbonitrile, cyclohexanecarbonitrile, cycloheptanecarbonitrile, phenylcyclohexanecarbonitrile, tolylcyclohexanecarbonitrile and the like.

Alcohols can be cyclic or non-cyclic, saturated or unsaturated, and are not particularly limited. In general, a saturated alcohol is preferably used.

Normally, alcohol having 1 to 20 carbon atoms, particularly alcohol having 1 to 12 carbon atoms, especially alcohol having 1 to 6 carbon atoms, particularly monovalent alcohol having 1 to 5 carbon atoms, divalent alcohol having 2 to carbon atoms or trivalent alcohol having 3 carbon atoms is preferably used. Specific examples of these alcohols include methanol, ethanol, 1-propanol, 2-propanol, 1-butanol, 2-butanol, isobutyl alcohol, tert-butyl alcohol, 1-pentanol, 2-pentanol, 3-pentanol, 2-methyl-1-butanol, isopentyl alcohol, tert-pentyl alcohol, 3-methyl-2-butanol, neopentyl alcohol, 1-hexanol, 2-methyl-1-pentanol, 4-methyl-2-pentanol, 2-ethyl-1-butanol, 1-heptanol, 2-heptanol, 3-heptanol, 1-octanol, 2-octanol, 2-ethyl-1-hexanol, 1-nonanol, 1-decanol, 1-undecanol, 1-dodecanol, allyl alcohol, propargyl alcohol, benzyl alcohol, cyclohexanol, 1-methylcyclohexanol, 2-methylcyclohexanol, 3-methylcyclohexanol, 4-methylcyclohexanol, 2-methoxyethanol, 2-ethoxyethanol, 2-(methoxymethoxy)ethanol, 2-isoproxy ethanol, 2-butoxy ethanol, 2-(isopentyloxy)ethanol, 2-(hexyloxy)ethanol, furfuryl alcohol, diethylene glycol monomethyl ether, diethylene glycol monoethyl ether, diethylene glycol monobutyl ether, triethylene glycol monomethyl ether, 1-methoxy-2-propanol, 1-ethoxy-2-propanol, dipropylene glycol monomethyl ether, dipropylene glycol monoethyl ether, tripropylene glycol monomethyl ether, 1,2-ethanediol, 1,2-propanediol, 1,3-propanediol, 1,2-butanediol, 1,3-butanediol, 1,4-butanediol, 2,3-butanediol, 1,5-pentanediol, 2-butene-1,4-diol, 2-methyl-2,4-pentanediol, 2-ethyl-1,3-hexanediol, diethylene glycol, triethylene glycol, tetraethylene glycol, polyethylene glycol, dipropylene glycol, polypropylene glycol, glycerol and the like.

Preferable examples of monovalent alcohol include methanol, ethanol, 1-propanol, 2-propanol, 1-butanol, 2-butanol, isobutyl alcohol, tert-butyl alcohol, 1-pentanol, 2-pentanol, 3-pentanol, 2-methyl-1-butanol, isopentyl alcohol, tert-pentyl alcohol, 3-methyl-2-butanol, neopentyl alcohol, 1-hexanol, 2-methyl-1-pentanol, 4-methyl-2-pentanol, 2-ethyl-1-butanol, 1-heptanol, 2-heptanol, 3-heptanol, 1-octanol, 2-octanol, 2-ethyl-1-hexanol, 1-nonanol, 1-decanol, 1-undecanol, 1-dodecanol, benzyl alcohol, cyclohexanol, 1-methylcyclohexanol, 2-methylcyclohexanol, 3-methylcyclohexanol, 4-methylcyclohexanol, 2-methoxyethanol, 2-ethoxyethanol, 2-(methoxymethoxy)ethanol and the like, and particularly, methanol, ethanol, 1-propanol, 2-propanol, 1-butanol, 2-butanol, isobutyl alcohol, tert-butyl alcohol, 1-pentanol, 2-pentanol, 3-pentanol, 2-methyl-1-butanol, isopentyl alcohol, tert-pentyl alcohol, 3-methyl-2-butanol, neopentyl alcohol, 1-hexanol, 2-methyl-1-pentanol, 4-methyl-2-pentanol, 2-ethyl-1-butanol, cyclohexanol and the like are preferable. Methanol, ethanol, 1-propanol, 2-propanol, 1-butanol, 2-butanol, isobutyl alcohol, tert-butyl alcohol, 1-pentanol, 2-pentanol, 3-pentanol, 2-methyl-1-butanol, isopentyl alcohol, tert-pentyl alcohol, 3-methyl-2-butanol, neopentyl alcohol and the like are particularly preferable.

Methanol, ethanol, 1-propanol, 2-propanol, 1-butanol, 2-butanol, isobutyl alcohol, 2-methyl-1-butanol, isopentyl alcohol and the like are most preferable. Methanol, ethanol, 1-propanol and 2-propanol are particularly preferable, and ethanol is especially preferable.

As divalent alcohol, 1,2-ethanediol, 1,2-propanediol, 1,3-propanediol, 2-butene-1,4-diol, 2-methyl-2,4-pentanediol, 2-ethyl-1,3-hexanediol, diethylene glycol, triethylene glycol, tetraethylene glycol, polyethylene glycol, dipropylene glycol, polypropylene glycol and the like are preferable. 1,2-propanediol and polyethylene glycol are most preferable. As a trivalent alcohol, glycerol is preferable.

Ketones are not particularly limited, and a ketone having 3 to 6 carbon atoms is generally preferable.

Specific examples of ketones include acetone, methylethylketone, methylbutylketone, methylisobutylketone and the like. Acetone and methylethylketone are preferable, and acetone is particularly preferable.

Examples of nitrogen compounds include nitromethane, acetonitrile, triethylamine, pyridine, formamide, N-methylformamide, N,N-dimethylformamide, N,N-dimethylacetamide, N-methylpyrrolidone and the like, and acetonitrile is particularly preferable.

Examples of sulfur compounds include dimethyl sulfoxide, sulfolane and the like. Dimethyl sulfoxide is preferable.

Examples of fatty acids include formic acid, acetic acid, propionic acid, oleic acid, linoleic acid, linolenic acid and the like. Formic acid and acetic acid are preferable, and acetic acid is more preferable.

Fats and oils are not particularly limited, and can be natural fats and oils from plants and animals, synthetic fats and oils or processed fats and oils.

Examples of vegetable oil include olive oil, coconut oil, palm oil, palm kernel oil, flaxseed oil, camellia oil, brown rice germ oil, canola oil, rice oil, peanuts oil, corn oil, wheat germ oil, soy bean oil, perilla oil, cottonseed oil, sunflower kerel oil, kapok oil, evening primrose oil, shea butter, sal butter, cacao butter, sesame oil, safflower oil and the like, and examples of animal fats and oils include lard, milk fat, fish oil, beef fat and the like. Furthermore, fats and oils obtained by processing them by fractionation, hydrogenation, transesterification (e.g., hydrogenated oil) and the like also can be used. Medium-chain triglyceride (MCT), partial glyceride of fatty acid, phospholipid and the like can also be used.

Examples of medium-chain triglyceride include triglyceride wherein the fatty acid has 6 to 12 carbon atoms, preferably 8 to 12 carbon atoms. Examples of partial glyceride of fatty acid include monoglyceride and diglycerides wherein the fatty acid has 6 to 18 carbon atoms, preferably 6 to 12 carbon atoms.

Of the above-mentioned fats and oils, vegetable fats and oils, synthetic fats and oils and processed fats and oils are preferable from the aspects of handlability, odor and the like.

Fats and oils are preferably selected in consideration of the price of fats and oils, stability of reduced coenzyme Q_{10}, solubility of coenzyme Q_{10} and the like.

For example, olive oil, coconut oil, palm oil, palm kernel oil, canola oil, rice oil, soy bean oil, cottonseed oil, MCT and the like are preferable, olive oil, rice oil, soy bean oil, canola oil, MCT and the like are particularly preferable.

From the aspect of the solubility of coenzyme Q_{10}, MCT can be particularly preferably used.

When the composition of the present invention is used for a food or pharmaceutical agent, ethanol, water and fats and oils usable for the food or pharmaceutical agent are preferably used, from among the above-mentioned solvents. The composition of the present invention can contain other appropriate materials, besides the above-mentioned solvent, such as a carrier. That is, the composition can comprise an excipient, disintegrant, lubricant, binder, antioxidant, coloring agent, anticoagulant, absorption promoter, solubilizing agent for the active ingredient, stabilizer, active ingredient other than reduced coenzyme Q_{10}, or combinations thereof. The carrier can be a pharmaceutically acceptable carrier.

The above-mentioned excipient is not particularly limited. For example, sucrose, lactose, glucose, cornstarch, mannitol, crystalline cellulose, calcium phosphate, calcium sulfate and the like can be used as an excipient.

The above-mentioned disintegrant is not particularly limited. For example, starch, agar, calcium citrate, calcium carbonate, sodium hydrogencarbonate, dextrin, crystalline cellulose, carboxymethylcellulose, tragacanth and the like can be used as a disintegrant.

While the above-mentioned lubricant is not particularly limited. For example, talc, magnesium stearate, polyethylene glycol, silica, hydrogenated vegetable oil and the like can be used as a lubricant.

The above-mentioned binder is not particularly limited. For example, ethylcellulose, methylcellulose, hydroxypropylmethylcellulose, tragacanth, shellac, gelatin, gum arabic, polyvinylpyrrolidone, polyvinyl alcohol, polyacrylic acid, polymethacrylic acid, sorbitol and the like can be used as a binder.

The above-mentioned antioxidant is not particularly limited. For example, ascorbic acid, tocopherol, vitamin A, β-carotene, sodium hydrogensulfite, sodium thiosulfate, sodium pyrrosulfite, citric acid and the like can be used as an antioxidant.

The above-mentioned coloring agent is not particularly limited. For example, those allowed to be added to pharmaceutical products and food and the like can be used as a coloring agent.

The above-mentioned anticoagulant is not particularly limited. For example, stearic acid, talc, light anhydrous silicic acid, water-containing silicon dioxide and the like can be used as an anticoagulant.

The above-mentioned absorption promoter is not particularly limited. For example, higher alcohols, higher fatty acids, sucrose fatty acid ester, surfactants such as sorbitan fatty acid ester, sorbitan polyoxyethylene fatty acid ester and the like, and the like can be used as an absorption promoter.

The solubilizing agent for the above-mentioned active ingredient is not particularly limited. For example, organic acids such as fumaric acid, succinic acid, malic acid and the like, and the like can be used as a dissolution aid.

The above-mentioned stabilizer is not particularly limited. For example, benzoic acid, sodium benzoate, ethyl parahydroxybenzoate and the like can be used as a stabilizer.

The active ingredient other than the above-mentioned coenzyme Q_{10} can be any other suitable active agent, such as an amino acid, vitamin, mineral, polyphenol, organic acid, saccharides, peptide, protein and the like.

While the amount of the reduced coenzyme Q_{10} contained in the composition of the present invention is not particularly limited, the weight of the reduced coenzyme Q_{10} contained in the whole composition is generally not less than about 0.01 wt %, preferably not less than about 0.1 wt %, more preferably not less than about 1 wt %, particularly preferably not less than about 2 wt %, and more preferably not less than about 3 wt %.

While the upper limit is not particularly limited, it is generally not more than about 70%, preferably not more than about 60 wt %, and more preferably not more than about 50 wt % in consideration of the viscosity of the composition and the like.

When practicing the present invention, the temperature is not particularly limited. To exhibit the reduced coenzyme Q_{10}-stabilizing effect to the maximum, the temperature is normally not more than 50° C., preferably not more than 40° C., more preferably not more than 30° C.

When processing into a dosage form for the oral administration mentioned below, moreover, the composition of the present invention is more preferably a liquid (including not only solution but also suspension, slurry or liposome) at ambient temperature or a temperature not less than the ambient temperature.

While the composition of the present invention can be used as it is, the composition can be processed into a dosage form for oral administration such as capsule (microcapsule, hard capsule, soft capsule), tablet, syrup, drink and the like and used preferably.

In addition, it can be processed into a dosage form for parenteral administration such as cream, suppository, toothpaste and the like and used preferably. Particularly preferred is a capsule, especially a soft capsule.

The capsule base material is not particularly limited, and gelatin derived from beef bones, cattle skin, pig skin, fish skin and the like, and other base materials (e.g., gum stabilizers) that can be used as food additives, such as seaweed-derived products (e.g., carageenan, alginic acid and the like), vegetable seed-derived products (e.g., locust bean gum, guar gum and the like), agents for production (e.g., celluloses) and the like) can also be used.

The stabilization method and production method of the present invention are preferable performed in combination under a deoxygenation atmosphere. That is, to exert the effect of the invention to the maximum extent, for example, the method of the present invention is preferably performed and the composition of the present invention is preferably prepared and/or preserved under a deoxygenation atmosphere such as inert gas atmosphere (e.g., nitrogen atmosphere etc.) and the like.

The above-mentioned processing and preservation after processing are also preferably performed under the above-mentioned deoxygenation atmosphere such as inert gas atmosphere and the like.

As mentioned above, by the co-presence of reduced coenzyme Q_{10} and reduced coenzyme Q_9 and/or reduced coenzyme Q_{11}, the stability of reduced coenzyme Q_{10} can be improved.

Reduced coenzyme Q_9 and reduced coenzyme Q_{11} exhibit the same effect as provided by reduced coenzyme Q_{10} in the body. Therefore, even when reduced coenzyme Q_9 and reduced coenzyme Q_{11} contained in the reduced coenzyme Q_{10} are ingested, they do not prevent the effect of the reduced coenzyme Q_{10} but act in the same manner as the reduced coenzyme Q_{10}.

The present inventors have moreover studied intensively and found that the absorbability of reduced coenzyme Q_9 in the body is greater than that of the reduced coenzyme Q_{10}.

As mentioned above, since reduced coenzyme Q_9 and reduced coenzyme Q_{10} act in the same manner in the body, a composition containing reduced coenzyme Q_9 and reduced coenzyme Q_{10} in combination is expected to show higher absorption of coenzyme Q as a whole.

According to the present invention, reduced coenzyme Q_{10} can be preferably protected from oxidation, and a composition free of an oxidation product of a reducing agent such as dehydroascorbic acids and the like can be provided optimally. Moreover, a composition showing high biological absorbability of reduced coenzyme Q_{10} can also be provided.

EXAMPLES

The present invention is explained in more detail in the following by referring to Examples, which are not to be construed as limitative.

In Examples, the purity of reduced coenzyme Q_{10}, and the weight ratio of reduced coenzyme Q_{10} and oxidized coenzyme Q_{10} were determined by HPLC analysis as discussed below. However, the purity of the obtained reduced coenzyme Q_{10} does not define the limit value of the purity in the present invention. Likewise, the proportion of reduced coenzyme Q_{10} in the weight ratio of reduced coenzyme Q_{10} and oxidized coenzyme Q_{10} does not define the upper limit value thereof.

(HPLC Analysis Conditions)

column: SYMMETRY C18 (manufactured by Waters) 250 mm (length) 4.6 mm (inner diameter), mobile phase; C_2H_5OH:CH_3OH=4:3 (v:v), detection wavelength; 210 nm, flow rate; 1 ml/min, retention time of reduced coenzyme Q_{10}; 9.1 min, retention time of oxidized coenzyme Q_{10}; 13.3 min.

Production Example 1

Oxidized coenzyme Q_{10} (100 g) and L-ascorbic acid (60 g) were added to 1000 g of ethanol, and the mixture was stirred at 78° C. to perform a reduction reaction. After 30 hr, the mixture was cooled to 50° C., and 400 g of ethanol was added while maintaining at the same temperature. The ethanol solution (containing 100 g of reduced coenzyme Q_{10}) was cooled to 2° C. at a cooling rate of 10° C./hr with stirring to give a white slurry. The obtained slurry was filtered under reduced pressure, the wet crystals were washed with cold ethanol, cold water and cold ethanol in this order (temperature of cold solvent used for washing, 2° C.) and dried under reduced pressure (20-40° C., 1-30 mmHg) to give white dry crystals (95 g). All operations except reduced-pressure drying were performed under a nitrogen atmosphere. The weight ratio of reduced coenzyme Q_{10}/oxidized coenzyme Q_{10} of the obtained crystals was 99.4/0.6.

Production Example 2

Oxidized coenzyme Q_9 (10 g) and L-ascorbic acid (7 g) were added to 100 g of ethanol, and the mixture was stirred at 78° C. to perform a reduction reaction. After 30 hr, the mixture was cooled to 50° C., and ethanol (40 g), hexane (140 g) and water (140 g) were added in this order while maintaining at the same temperature. After removing the aqueous layer, the organic layer was concentrated under reduced pressure to give reduced coenzyme Q_9 as crystals.

Production Example 3

The reduced coenzyme Q_{10} (9.85 g) obtained in Production Example 1 and reduced coenzyme Q_9 (0.15 g) obtained in Production Example 2 were mixed to give reduced coenzyme Q_{10} containing 1.5 wt % of reduced coenzyme Q_9 (reduced coenzyme Q_{10}/oxidized coenzyme Q_{10}=99.4/0.6).

Production Example 4

Oxidized coenzyme Q_{10} (10 g) containing 0.1% of oxidized coenzyme Q_{11} and L-ascorbic acid (6 g) were added to 100 g of ethanol, and the mixture was stirred at 78° C. to perform a reduction reaction. After 30 hr, the mixture was cooled to 50° C., and 40 g of ethanol and water (10 g) were added while maintaining the same temperature. The ethanol solution (containing 10 g of reduced coenzyme Q_{10}) was cooled to 2° C. at a cooling rate of 10° C./hr with stirring to give a white slurry. The obtained slurry was filtered under reduced pressure, the wet crystals were washed with cold ethanol, cold water and cold ethanol in this order (temperature of cold solvent used for washing, 2° C.) and dried under reduced pressure (20-40° C., 1-30 mmHg) to give white dry crystals (9.5 g). All operations except reduced-pressure drying were performed under a nitrogen atmosphere. The obtained crystals contained 0.1% of reduced coenzyme Q_{11} and the weight ratio of reduced coenzyme Q_{10}/oxidized coenzyme Q_{10} of the obtained crystals was 99.4/0.6.

Example 1

The reduced coenzyme Q_{10} (reduced coenzyme Q_{10}/oxidized coenzyme Q_{10}=99.4/0.6) containing 1.5 wt % of reduced coenzyme Q_9 obtained in Production Example 3 and crystals of reduced coenzyme Q_{10} (reduced coenzyme Q_{10}/oxidized coenzyme Q_{10}=99.4/0.6) free of reduced coenzyme Q_9, which were obtained in Production Example 1, were maintained in a condition exposed to air at 25° C. The results of reduced coenzyme Q_{10}/oxidized coenzyme Q_{10} ratio after the lapse of 24 hr are shown in Table 1.

TABLE 1

	weight ratio of reduced coenzyme Q_{10}/oxidized coenzyme Q_{10}
reduced coenzyme Q_{10} containing 1.5% of reduced coenzyme Q_9	96.7/3.3
reduced coenzyme Q_{10} free of reduced coenzyme Q_9	95.5/4.5

Example 2

50 mg of the reduced coenzyme Q_{10} (reduced coenzyme Q_{10}/oxidized coenzyme Q_{10}=99.4/0.6) containing 1.5 wt % of reduced coenzyme Q_9 obtained in Production Example 3 or 50 mg of reduced coenzyme Q_{10} (reduced coenzyme Q_{10}/oxidized coenzyme Q_{10}=99.4/06) free of reduced coenzyme Q_9, which were obtained in Production Example 1, was added to 5 g of ethanol and stirred in the air at 25° C. The resulting reduced coenzyme Q_{10}/oxidized coenzyme Q_{10} ratio after stirring for 6 hr are shown in Table 2.

TABLE 2

	weight ratio of reduced coenzyme Q_{10}/oxidized coenzyme Q_{10}
reduced coenzyme Q_{10} containing 1.5% of reduced coenzyme Q_9	90.2/9.8
reduced coenzyme Q_{10} free of reduced coenzyme Q_9	87.2/12.8

Example 3

Crj:CD (SD) rats (5-week-old, 15 males, 15 females, body weight 260 g-300 g) were divided into 3 groups (5 per group) for each of male and female. A first group was used as a control group, and corn oil (3 ml/kg) was orally administered once a day for 14 days. A second group was orally administered a corn oil solution of the reduced coenzyme Q_9 obtained in Production Example 2, which was prepared to meet the dose of reduced coenzyme Q_9 of 600 mg/kg, once a day for 14 days at a dose of 3 ml/kg. A third group was orally administered a corn oil solution of reduced coenzyme Q_{10} obtained in Production Example 1, which was prepared to meet the dose of reduced coenzyme Q_{10} of 600 mg/kg, once a day for 14 days at a dose of 3 ml/kg. At 24 hr after the final administration, blood samples were collected to give plasma samples. Using HPLC, the concentration of coenzyme Q in the obtained plasma was measured. The results are shown in the bar graph of FIG. **1**.

In FIG. **1**, the vertical axis shows the concentration of total coenzyme Q in the plasma, and each bar shows the average±standard deviation. As is clear from FIG. **1**, in both male and female, the concentration of total coenzyme Q in the plasma increased in the reduced coenzyme Q_9 administration group as compared to the reduced coenzyme Q_{10} administration group.

Preparation Example

To a mixture of canola oil, diglycerol monooleate (Poem DO-100 V manufactured by Riken Vitamin), hydrogenated oil, bees wax and lecithin were added crystals of reduced coenzyme Q_{10} containing 0.6 wt % of oxidized coenzyme Q_{10} and 0.1 wt % of reduced coenzyme Q_{11}, and a soft capsule of gelatin containing 30 mg of reduced coenzyme Q_{10} and having the following formulation was prepared by a conventional method.

reduced coenzyme Q_{10}	10.0 wt %
diglycerolmonooleate	32.0 wt %
canola oil	33.0 wt %
hydrogenated oil	17.0 wt %
bees wax	6.0 wt %
lecithin	2.0 wt %

Example 4

Oral Absorbability Test

Crj:CD (SD) rats (about 77-week-old, 10 male rats) were prepared. Reduced coenzyme Q_{10} was orally administered to 5 of them, and a mixture of reduced coenzyme Q_{10} and reduced coenzyme Q_{11} (containing 0.1% of reduced coenzyme Q_{11}) was orally administered to the remaining 5 of them, each as a 25 mg/ml soy bean oil solution at a dose of 4.0 ml/kg. At 2 hr from the administration, blood was drawn and centrifuged to give plasma samples. Using HPLC, the concentration of coenzyme Q_{10} in the obtained plasma was measured. The results are shown in the bar graph of FIG. **2**. As is clear from FIG. **2**, the concentration of coenzyme Q_{10} in the plasma was about 3.4 μg/ml resulting from the administration of both reduced coenzyme Q_{10} and a mixture of reduced coenzyme Q_{10} and reduced coenzyme Q_{11}.

While some of the embodiments of the present invention have been described in detail above, those of ordinary skill in the art can enter various modifications and changes to the particular embodiments shown without substantially departing from the novel teaching and advantages of the present invention. Such modifications and changes are encompassed in the spirit and scope of the present invention as set forth in the appended claims.

This application is based on application No. 2006-126897 filed in Japan, the contents of which are incorporated hereinto by reference.

The invention claimed is:

1. A method for stabilizing reduced coenzyme Q_{10}, which method comprises preparing a reduced coenzyme Q_{10}-containing composition comprising reduced coenzyme Q_{10} and one or both of (a) and (b):

(a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}, and

(b) reduced coenzyme Q_{11},

wherein not less than 0.01 wt % of reduced coenzyme Q_{10} is contained in the composition, and

wherein the proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} is not less than 90 wt %,

thereby stabilizing reduced coenzyme Q_{10}.

2. The method of claim **1**, wherein the method comprises preparing one or both of (a) the reduced coenzyme Q_9 and (b) the reduced coenzyme Q_{11}, and then

adding one or both of (a) the reduced coenzyme Q_9 and (b) the reduced coenzyme Q_{11} to the reduced coenzyme Q_{10} to prepare the reduced coenzyme Q_{10}-containing composition.

3. The method of claim **1**, wherein the method comprises providing a composition comprising oxidized coenzyme Q_{10} with one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11}, and then

reducing oxidized coenzyme Q_{10} and reducing one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11} to prepare the reduced coenzyme Q_{10}-containing composition.

4. The method of claim **1**, wherein the reduced coenzyme Q_{10}-containing composition is prepared under a deoxygenation atmosphere.

5. A reduced coenzyme Q_{10}-containing composition comprising reduced coenzyme Q_{10} and one or both of (a) and (b):

(a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}, and

(b) reduced coenzyme Q_{11}

wherein not less than 0.01 wt % of reduced coenzyme Q_{10} is contained in the composition, and

wherein the proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} is not less than 90 wt %.

6. The composition of claim **5**, wherein the reduced coenzyme Q_{10} is in crystalline form.

7. The composition of claim 5, wherein the reduced coenzyme Q_{10} is dissolved or suspended in a solvent.

8. The composition of claim 5, wherein the reduced coenzyme Q_{10} is a melt.

9. The composition of claim 5, which further comprises a pharmaceutically acceptable carrier.

10. The composition of claim 5, which is in a form suitable for administration to a mammal and comprises reduced coenzyme Q_{10} as an active ingredient.

11. The composition of claim 5, which further comprises at least one component selected from the group consisting of an excipient, a disintegrant, a lubricant, a binder, an antioxidant, a coloring agent, an anticoagulant, an absorption promoter, a solubilizing agent for the active ingredient, a stabilizer, an active ingredient other than reduced coenzyme Q_{10}, and combinations thereof.

12. An oral dosage form comprising the composition of claim 11, which dosage form is a capsule.

13. The oral dosage form of claim 12, wherein the capsule is a microcapsule, a soft capsule, or a hard capsule.

14. A method for producing a reduced coenzyme Q_{10}-containing composition, which method comprises

preparing one or both of (a) reduced coenzyme Q_9 and (b) reduced coenzyme Q_{11}, and then

adding one or both of (a) the reduced coenzyme Q_9 and (b) the reduced coenzyme Q_{11} to reduced coenzyme Q_{10} to prepare the reduced coenzyme Q_{10}-containing composition,

wherein the composition comprises reduced coenzyme Q_{10} and one or both of (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10} and (b) reduced coenzyme Q_{11},

wherein not less than 0.01 wt % of reduced coenzyme Q_{10} is contained in the composition, and

wherein the proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} is not less than 90 wt %.

15. A method for producing a reduced coenzyme Q_{10}-containing composition, which method comprises

providing a composition comprising oxidized coenzyme Q_{10} with one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11}, and then

reducing oxidized coenzyme Q_{10} and reducing one or both of oxidized coenzyme Q_9 and oxidized coenzyme Q_{11} to prepare the reduced coenzyme Q_{10}-containing composition,

wherein the composition comprises reduced coenzyme Q_{10} and one or both of (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10} and (b) reduced coenzyme Q_{11},

wherein not less than 0.01 wt % of reduced coenzyme Q_{10} is contained in the composition, and

wherein the proportion of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10} is not less than 90 wt %.

16. The composition of claim 5, wherein the reduced coenzyme Q_{10}-containing composition comprises not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q_9 relative to reduced coenzyme Q_{10}.

17. The composition of claim 5, wherein the reduced coenzyme Q_{10}-containing composition comprises reduced coenzyme Q_{11}.

18. The composition of claim 5, wherein the reduced coenzyme Q_{10}-containing composition comprises not less than 96 wt % of reduced coenzyme Q_{10} relative to the total amount of coenzyme Q_{10}.

* * * * *

EXHIBIT B

CoQ10 Benefits

(http://floridacoq10.com/)

How does this supplement work?

Coenzyme Q10 (http://floridacoq10.com/faq-on-coq10-supplements/) is an excellent supplement to take. This supplement will help mitigate the risks and development of heart and kidney failure, gingivitis, migraines, hypertension, preventing and healing for heart attacks, diabetes, Parkinson's, weight loss and more.

In terms of your heart, scientific studies have revealed that people who have dealt with heart issues typically have very low levels of Coenzyme Q10 within the cells of their heart. These experiments have suggested that taking this supplement on a regular basis can help reduce the likelihood of dealing with these types of heart issues. It also reduces the symptoms, including swelling, insomnia and short breath. CoQ10 does this by boosting the energy in the heart cells, which works to increase the strength that your heart pumps.

If you have any questions (http://floridacoq10.com/faq-on-coq10-supplements/) related to your health and how the supplement will affect it, you need to make sure that you reach out to your doctor or another health professional. Your doctor will give you an evaluation and let you know if you have any kinds of health issues that might react with any type of supplement. Always do your due diligence in this regard, so that you can make the most of your supplement shopping.

Kaneka Corp.'s patented ubiquinol nutrient, Kaneka QH Ubiquinol®, is the world's first and only bio-identical ubiquinol (http://floridacoq10.com/ubiquinol-coq10/) available for use in supplements. To learn more, visit http://ubiquinol.org (http://ubiquinol.org/)

EXHIBIT C

New Ubiquinol—CoQ10 Finally Comes of Age

An exclusive interview with Robert Barry, Ph.D.

While visiting the world's largest manufacturer of CoQ10 (/coq10), Kaneka Nutrients, in Houston, I had the pleasure of meeting with Dr. Robert Barry, who shared with me his personal experiences with CoQ10 and Kaneka's new, biologically active Q10 supplement, Ubiquinol (/ubiquinol). Following are some highlights from our discussions.

Lee Swanson *~Lee Swanson, President of Swanson Health Products*

Dr. Robert Barry

Dr. Robert Barry, Chief of Scientific Affairs for Kaneka Nutrients, LP, earned his bachelor's degree in biology from Boston College, his Ph.D. in chemistry/biochemistry from the University of Maryland, did postdoctoral research in Biological Chemistry and Molecular Pharmacology at Harvard Medical School, and was a staff researcher in neuropathology at Harvard Medical School. He has served as a principle advisor for the National Institutes of Health. Prior to joining Kaneka, Dr. Barry founded a company focused on identifying new lead-drug candidates.

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SWANSON: Thank you for taking the time to meet with me today. I'm very excited about this new development in CoQ10 supplementation. Can you tell our readers what makes it so special?

DR. BARRY: It's a pleasure to meet you, Lee. Let me start by saying that this new development does not render your original CoQ10 obsolete; rather, it's a new alternative form better suited for more advanced uses and for those of truly advanced years. That being said, what exactly is Ubiquinol as opposed to Q10? Basically, it's a molecular difference. Functionally, it can be several times more effective at increasing blood CoQ10 levels. You see, original CoQ10 supplements contain what is known as "ubiquinone," which is the oxidized form of the nutrient as it is found in foods. But over 90 percent of the CoQ10 that is stored and used in the body is in the form of "ubiquinol," which is a reduced form of the ubiquinone molecule. When you ingest ubiquinone, your body metabolizes it, creating the reduced Ubiquinol form. Kaneka's Ubiquinol (Kaneka QH®) is the first stabilized supplemental form of bio-identical ubiquinol ever developed. It took our scientists years to create a process that stabilizes this highly reactive and unstable substance, but it's finally here and we're very excited about it.

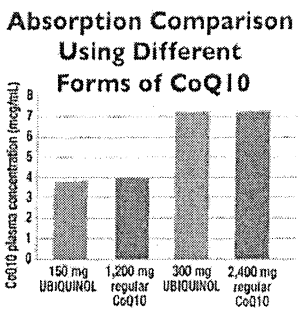
SWANSON: Is there clinical data on Ubiquinol?

DR. BARRY: First, let me say that the CoQ10 Kaneka produces is the exact form used by scientific researchers in 99 percent of published studies. We are one of the only companies that produces 100 percent natural CoQ10 through a biological fermentation process. And our CoQ10 is the only CoQ10 ingredient with extensive safety data. Our new Ubiquinol follows a similar research and production model. In fact, it begins with our original CoQ10, which is further refined and reduced into ubiquinol through a series of patented processes. We have many patents on Ubiquinol alone. As for research specifically on Ubiquinol, we have papers demonstrating stability, papers demonstrating safety, and papers demonstrating efficacy.

Just 150 mg of Ubiquinol can produce the same plasma level increases as 1,200 mg of conventional Q10—that's an almost eight-fold advantage!

The existing data on CoQ10 in terms of benefits applies to Ubiquinol, because once it's in the body, ubiquinone becomes ubiquinol. The exciting thing is that, according to the studies done thus far, we can achieve much higher blood levels with a much smaller dose using Ubiquinol. Just 150 mg of Ubiquinol can produce the same plasma level increases as 1,200 mg of conventional CoQ10—that's almost an eight-fold advantage (see graph).

SWANSON: Why, if Ubiquinol is so much more bioavailable, shouldn't everyone make the switch from their current Q10?



Based on published research, it takes nearly 8 times more CoQ10 to achieve the same blood levels produced with lower doses of UBIQUINOL.

DR. BARRY: That's a good question, and it really comes down to age and need. Younger, healthy individuals will do just fine continuing with conventional CoQ10. It's safe; it's effective; and it's affordable. Because of the unstable nature of Ubiquinol and the added production costs, it's a more expensive intervention—and that's what it's suited for: intervention. Ubiquinol is best suited for people over 50 years of age who have, for one reason or another, substantially lower CoQ10 levels. Unfortunately, testing Q10 levels is not as commonplace as we would like. Doctors can do it, but it's costly because the test has to be performed by a third-party lab. Fortunately, however, it's easy to ascertain in general who needs advanced CoQ10 supplementation. Elderly people are likely to find increased benefits with Ubiquinol.

Part of the equation is health status, but another part is simple aging. Not only does the body produce less CoQ10 as it ages, it also loses some of its ability to absorb it from foods or supplements and convert it to Ubiquinol. So at 80 years of age, the CoQ10 supplement you were taking when you were 40 is not performing the same for you. People at this life stage may want to consider Ubiquinol.

SWANSON: Thank you for sharing this information with us and for all the work you do with CoQ10 and now Ubiquinol. I encourage our readers to read more about the evidence—and the importance—of this powerful supplement.

Read more

The History of CoQ10 (/health-library/products/ubiquinol-50-years.html)

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EXHIBIT D

What Does the FDA Have to Say About Supplements?

By: John Jarmul (/john-jarmul) 11/25/2013

Many people voice concern about the notion that supplements aren't regulated by the U.S. Food and Drug Administration. While it's true the FDA doesn't regulate vitamins and supplements in the same way the federal agency regulates food and prescription medications, the 1994 Dietary Supplement Health and Education Act (DSHEA) created a new regulatory framework for dietary supplements, including regulations about the safety and labeling of supplements.

Although dietary supplements do not need FDA approval before they are marketed to the public, under the 1994 act, manufacturers and distributors of supplements are responsible for ensuring the safety of their products, and must have evidence based on clinical studies or other research that supports any claims they make about what a supplement does or is designed to do.

The DSHEA also requires supplement manufacturers to properly label their products. Labels must include a complete list of ingredients and nutrition labeling that includes a "Supplement Facts" panel. The label must also provide a descriptive name of the product that clearly states it is a

"supplement" as well as the name and address of the manufacturer, packer or distributor. Manufacturers are required to notify the FDA when introducing a "new dietary ingredient," which requires the ingredient to be reviewed for safety before it hits the market. This is a process Kaneka Corporation went through when it brought its KanekaQH™ Ubiquinol to the market in 2006. Manufacturers also have to register with the FDA before producing or selling supplements.

Kaneka developed and patented KanekaQH™, the world's first and only Ubiquinol available for use in supplements. Ubiquinol is the reduced, active antioxidant form of Coenzyme Q10 (or CoQ10), a nutrient your body naturally produces then converts into Ubiquinol. Your body needs Ubiquinol for its cellular energy production process. Ubiquinol also helps maintain the health of your heart, liver, kidneys and brain and can boost energy levels. As the most powerful known fat-soluble antioxidant, Ubiquinol can protect your cells, tissue and organs from damage caused by oxidative stress and free radicals.

CoQ10 supplements have been available for more than 30 years, but study after study has demonstrated that Ubiquinol is actually more effective than CoQ10, especially for anyone over the age of 30.As we age, our bodies become less efficient at converting CoQ10 to Ubiquinol. With Ubiquinol supplements, the conversion from CoQ10 has already been done outside your body, so the Ubiquinol is ready for immediate use. Every study to date shows that individuals can more easily absorb and use Ubiquinol than conventional CoQ10.

Today, there are many brands of Ubiquinol supplements on the market, but all of them use Kaneka's patented Ubiquinol in their products. Although each manufacturer must follow FDA regulations regarding supplements, it's up to you as the consumer to evaluate the individual brands to decide which is best for you.

So how do you determine which supplement, Ubiquinol or otherwise, is best for you? Read the label, familiarize yourself with the list of ingredients and check the "Supplement Facts" panel on the bottle or box. Kaneka QH™ Ubiquinol is the main ingredient in more than 135 brand-name supplements. Companies that make and sell Ubiquinol supplements include Nature Made, Nature's Plus, Doctor's Best and Puritan's Pride. Several national retailers, including The Vitamin Shoppe, GNC and Trader Joe's, also make and sell their own store brands of Ubiquinol supplements.

Ubiquinol supplements are widely available at pharmacies, vitamin shops and in the supplement aisle or health section of most grocery stores. When shopping, you should be aware that Ubiquinol is often labeled as "CoQ10 Ubiquinol" and is usually stocked on the same shelf or in the same area as conventional CoQ10 supplements. To avoid confusion, check the FDA-required Supplement Facts label on the bottle for "Ubiquinol (Kaneka QH™)." Authentic Ubiquinol products include the Kaneka QH logo, so you can be certain you are buying the right form of CoQ10.

The recommended daily maintenance dose of Ubiquinol is 100 mg per day, with some experts recommending 200-300mg a day for those who need it most. Many Ubiquinol supplements contain 100 mg per serving (i.e., per softgel or capsule), but check the amount on the Supplement Facts label to be sure as many brands now offer 200 or 300 mg softgels to reduce the number of pills you need to take.

Although vitamins and dietary supplements do not need approval from the FDA before they are sold to the public, consumers can have confidence that the FDA has regulations for supplement manufacturers and distributors. Pay attention to the Supplement Facts label and other important information on the bottle to help make an informed decision about what supplements are right for you!

Author: John Jarmul (/john-jarmul)

John Jarmul is the Marketing Manager for the Nutrients Division at Kaneka. He is an expert on heart health and a contributor to multiple medical related blogs. John lives in Houston, TX.

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Buyer's Guide

Get the facts about Ubiquinol and learn how a Ubiquinol supplement may benefit you