

June 20, 2005

Reid / VL
JUN 21 2005

Ms. Vickey Lutwak
Office of Nutritional Products, Labeling,
and Dietary Supplements HFS-810
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Revised New Dietary Ingredient Notification (KANEKA QH™
Brand of Ubiquinol)

Dear Ms. Lutwak:

In a conference call between representatives of FDA and CANTOX U.S. Inc., on June 14, 2005, the FDA requested additional clarification related to specific areas of the revised New Dietary Ingredient Notification for KANEKA QH™ brand of ubiquinol. Pursuant to that discussion, CANTOX respectfully submits the following additional information:

1. A reference for the CAS RN for ubiquinol obtained from ChemIDplus database. In addition, a reference for the alternate CAS RN (992-78-9) included in the submission was also provided.
2. English translations of the following three articles originally published in Japanese

Notake, Y., Tamura, S., Toyoshima, S., Fujita, H., Suzuki, Y. and Chiba, T. 1972. Effects of coenzyme Q10 on development of the fetuses and neonates in rats and mice. *Iyakuhin Kenkyu* 3(3):306-315.

Chiba, T.; Watanabe, T.; Kume, Y.; Sugiyama, K.; Shiojiri, H. 1972a. Toxicological studies of ubiquinone-10 (I) Acute toxicity test in rats and mice and subacute and chronic toxicity tests in rats. *Oyo Yakuri* 6:769-779.

Chiba, T.; Sugiyama, K.; Kume, Y.; Shiojiri, H.; Watanabe, T.; Ozeki, M. 1972b. Toxicological studies of ubiquinone-10 (II) Subacute toxicity test in rabbits. *Oyo Yakuri* 6:781-786.

3. A more detailed explanation of the methodology for measuring the ubiquinol content of various foods “using high-performance liquid chromatography (HPLC) with an electro chemical detector,” with particular attention to the identity of the standards used to differentiate between the oxidized and reduced forms of CoQ₁₀.

These items were also faxed to your attention at FDA on June 20, 2005.

Respectfully,

A handwritten signature in cursive script that reads "David H. Bechtel".

David H. Bechtel, Ph.D., DABT
Managing Director & Sr. Scientific Consultant

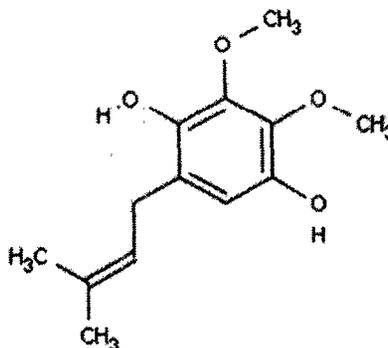
CAS Registry number for ubiquinol



ChemIDplus Advanced

▶ [Tox. & Env. Health](#) ▶ [TOXNET](#) ▶ [Return to Results Page](#)

Ubiquinol
RN: 56275-39-9
MW: null

**Names and Synonyms****Name of Substance**

Ubiquinol

Synonyms

- Ubiquinols
 Ubiquinone hydroquinone

Systematic Name

Ubiquinol

Registry Numbers**CAS Registry Number**

56275-39-9

System Generated Number

056275399

Locators**File Locator**

CANCERLIT

CANCER LITerature from Medline

MEDLINE

MEDical literature onLINE

MESH

Medical Subject Headings File

TOXLINE Core

NLM TOXLINE Core from MEDLINE

Customer Service: tehip@tehi.nlm.nih.gov.
Last modified on September 9, 2004.

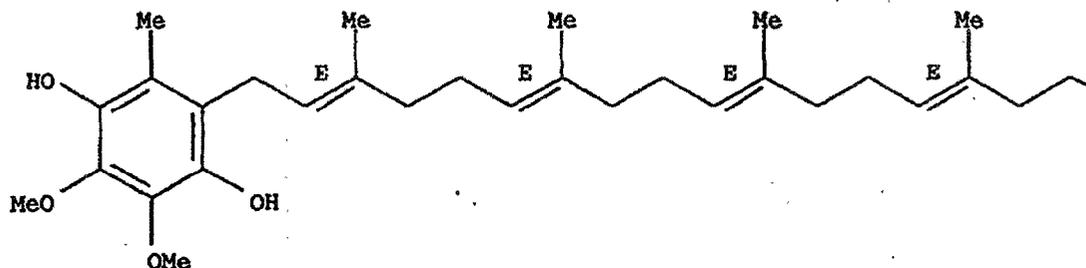
Registry Number:

992-78-9

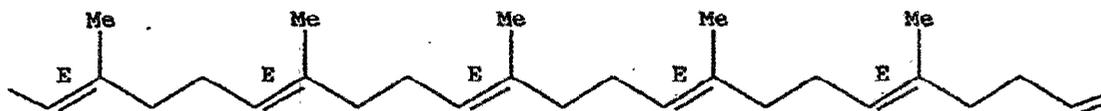
QH

Double bond geometry as shown.

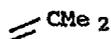
PAGE 1-A



PAGE 1-B



PAGE 1-C



Formula:

C59 H92 O4

CA Index Name:

1,4-Benzenediol,
2-[(2E,6E,10E,14E,18E,22E,26E,30E,34E)-3,7,11,15,19,23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl]-5,6-dimethoxy-3-methyl-(9CI)

Other Names:

1,4-Benzenediol,
2-(3,7,11,15,19,23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl)-5,6-dimethoxy-3-methyl-, (all-E)-; Hydroquinone,
2-(3,7,11,15,19,23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl)-5,6-dimethoxy-3-methyl- (6CI,7CI,8CI); Coenzyme Q10, dihydro-; Coenzyme Q10-hydroquinone; Dihydrocoenzyme Q10; Reduced coenzyme Q10; Reduced ubiquinone Q10; Ubiquinol 50

-- Properties --

Property	Calculated Value	Condition	Note
Bioconc. Factor	1.00E6	pH 1	(1) ACD
Bioconc. Factor	1.00E6	pH 4	(1) ACD
Bioconc. Factor	1.00E6	pH 7	(1) ACD

***** Welcome to STN International *****

FILE 'HOME' ENTERED AT 13:37:21 ON 16 JUN 2005

=> FILE REGISTRY

COST IN JAPANESE YEN	SINCE FILE ENTRY	TOTAL SESSION
FULL ESTIMATED COST	27	27

FILE 'REGISTRY' ENTERED AT 13:37:28 ON 16 JUN 2005

USE IS SUBJECT TO THE TERMS OF YOUR STN CUSTOMER AGREEMENT.

PLEASE SEE "HELP USAGETERMS" FOR DETAILS.

COPYRIGHT (C) 2005 American Chemical Society (ACS)

Property values tagged with IC are from the ZIC/VINITI data file provided by InfoChem.

STRUCTURE FILE UPDATES: 14 JUN 2005 HIGHEST RN 852282-01-0

DICTIONARY FILE UPDATES: 14 JUN 2005 HIGHEST RN 852282-01-0

New CAS Information Use Policies, enter HELP USAGETERMS for details.

=> S 992-78-9

L1 1 992-78-9
(992-78-9/RN)

=> D

L1 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2005 ACS on STN

RN 992-78-9 REGISTRY

ED Entered STN: 16 Nov 1984

CN 1,4-Benzenediol, 2-[(2E,6E,10E,14E,18E,22E,26E,30E,34E)-3,7,11,15,19,23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl]-5,6-dimethoxy-3-methyl- (9CI) (CA INDEX NAME)

OTHER CA INDEX NAMES:

CN 1,4-Benzenediol, 2-(3,7,11,15,19,23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl)-5,6-dimethoxy-3-methyl-, (all-E)-

CN Hydroquinone, 2-(3,7,11,15,19,23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl)-5,6-dimethoxy-3-methyl- (6CI, 7CI, 8CI)

OTHER NAMES:

CN Coenzyme Q10, dihydro-

CN Coenzyme Q10-hydroquinone

CN Dihydrocoenzyme Q10

CN Reduced coenzyme Q10

CN Reduced ubiquinone Q10

CN Ubiquinol 50

FS STEREOSEARCH

DR 30291-37-3

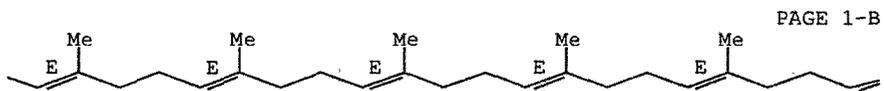
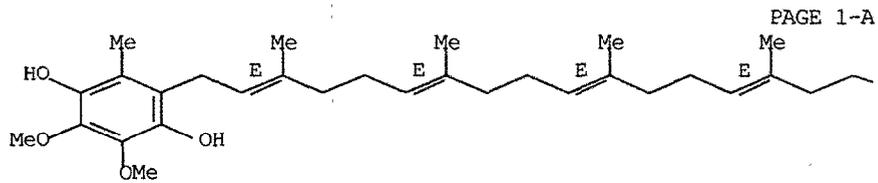
MF C59 H92 O4

CI COM

LC STN Files: AGRICOLA, BEILSTEIN*, CA, CAOLD, CAPLUS, CASREACT, CIN, IFICDB, IFIPAT, IFIUDB, TOXCENTER, USPATFULL

(*File contains numerically searchable property data)

Double bond geometry as shown.



PAGE 1-C

= CMe2

****PROPERTY DATA AVAILABLE IN THE 'PROP' FORMAT****

100 REFERENCES IN FILE CA (1907 TO DATE)
1 REFERENCES TO NON-SPECIFIC DERIVATIVES IN FILE CA
100 REFERENCES IN FILE CAPLUS (1907 TO DATE)
8 REFERENCES IN FILE CAOLD (PRIOR TO 1967)

=> LOG H

Translation:

Notake, Y., Tamura, S., Toyoshima, S., Fujita, H., Suzuki, Y. and Chiba, T. 1972.
Effects of coenzyme Q10 on development of the fetuses and neonates in rats and mice.
Iyaku-hin Kenkyu 3(3):306-315.