

DL-alpha TOCOPHERYL ACETATE

Definition

Acetic Acid Ester of all-racemic (DL) alpha-Tocopherol, belonging to the group of oil-soluble Vitamins, Universal Vitamin E-standard (1mg=1IU)

Synonymous names

Tocopherol (as a group name)
all-rac alpha Tocopheryl-Acetate
DL Acetyl-alpha-Tocopherol
Vitamin E Acetate
synthetical Vitamin E Acetate
Acétate de DL alpha tocophérol
DL alpha-Tocopheroli acetas

Old (obsolete) names from literature

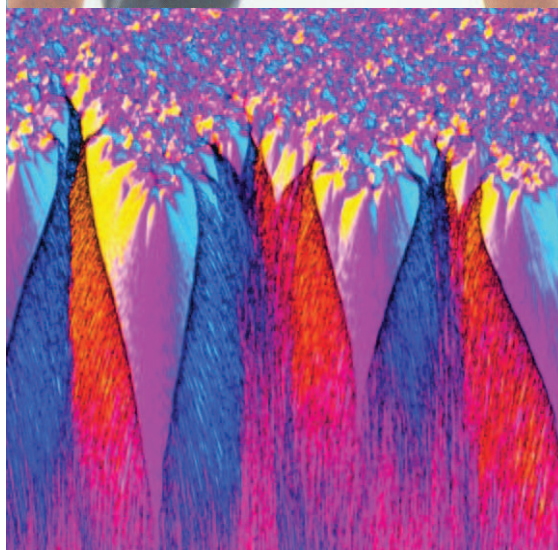
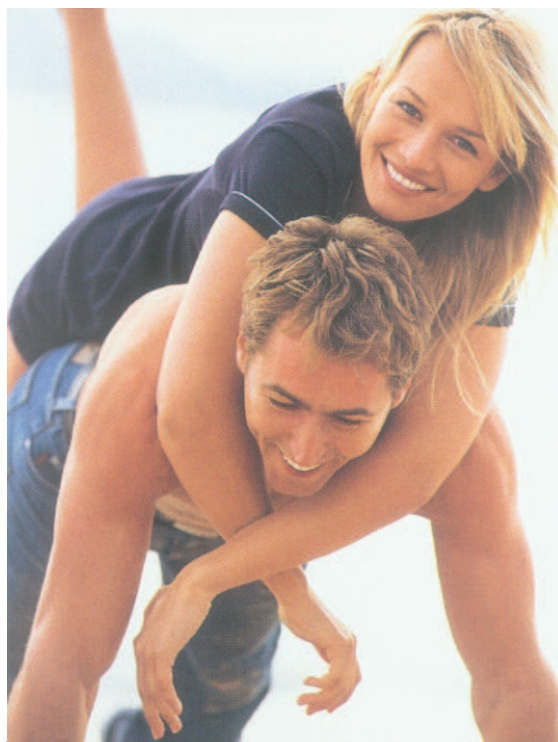
Antisterility Vitamin
Fertility Vitamin
Antidystrophic Vitamin

Chemical names

(2RS)-2,5,7,8-tetramethyl-2-[(4RS,8RS)-4,8,12-trimethyltridecyl]-chroman-6-yl-acetate (Ph.Eur.);
(2RS,4'RS,8'RS)-6-acetoxy-2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)-chroman (BP);
DL-6-acetoxy-2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)chroman;
(2RS)-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-6-chromanylacetat (IUPAC);

Official adopted names and nomenclatures

CAS No.: 7695-91-2
EINECS No.: 231-710-0
IUPAC/IUP: Tocopherols
INN name (WHO): no application
Declaration Food: Vitamin E
INCI name: Tocopheryl Acetate
CN Code: 2936 2800
Vitamin E and its derivatives



Producer: ZHEJIANG MEDICINE CO. Ltd./China

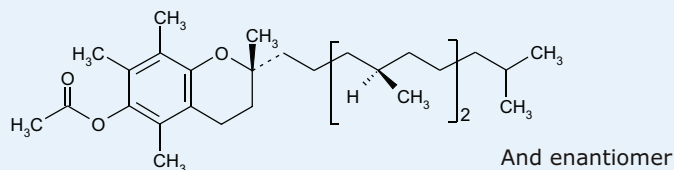


Kyowa Hakko Europe GmbH
Daiichi Fine Chemical Division

SPECIFICATION*

Chemical Name: (2RS)-2,5,7,8-tetramethyl-2[(4RS, 8RS)-4,8,12-trimethyltridecyl]chroman-6-yl-acetate

Chemical Structure:



Empirical formula: $C_{31}H_{52}O_3$

Molecular weight: 472.7

Appearance: Clear, yellow or greenish yellow viscous oil, odourless and tasteless

Identification: A: Specific optical rotation
B: IR Absorption Spectrophotometry
C: TLC test

Related substances:

impurity A*:	not more than 0,5 %
impurity B*:	not more than 1,5 %
impurity C*:	not more than 0,5 %
impurity D* and E*:	not more than 1,0 %
any other impurity	not more than 0,25 %
total impurities	not more than 2,5 %

Assay/vitamin E content not less than 96.5 % and not more than the equivalent of 102.0% of $C_{31}H_{52}O$

*¹ all-rac-trans-2,3,4,6,7-pentamethyl-2-(4,8,12-trimethyltridecyl)-2,3-dihydrobenzofuran-5-yl acetate

*² all-rac-cis-2,3,4,6,7-pentamethyl-2-(4,8,12-trimethyltridecyl)-2,3-dihydrobenzofuran-5-yl acetate

*³ all rac-alpha-tocopherol

*⁴ 4-methoxy-2,3,6-trimethyl-5-[(all-RS,E)-3,7,11,15-tetramethylhexadec-2-enyl]phenyl acetate

*⁵ (all-RS,all-E)-2,6,10,14,19,23,27,31-octamethyldotriaconta-12,14,18-triene

*meets the quality requirements of the current Ph. Eur. Monograph for all-rac- α Tocopheryl Acetate

Other physico-chemical properties

Manufacturing route: pure synthetical synthesis route, not involving any materials of animal origin or gene technology

Storage and packaging

Storage: Protect against heat, humidity and light
keep in an inert environment (store only under N_2 -blanket)

Standard Packaging: 5 kg aluminium tin
20 kg metal drums with removable lid and pourable spout opening
200 kg metal drum
950 kg IBC

Expiry Date: In unopened original packaging and under adequate storage conditions minimum 3 years after production date

Formulating

Standardization:	1.00 mg D-alpha Tocopherol equivalent = 1.49 mg DL-alpha Tocopheryl Acetate 1 mg (all-rac) DL-alpha Tocopheryl Acetate = 1.00 USP-unit 1 mg DL-alpha Tocopheryl Acetate = 1.00 IU (international Unit) Vitamin E
Stability:	DL-alpha Tocopheryl Acetate is regarded as one of the more stable vitamins, that means, under the prevailing processing conditions in cosmetics it keeps its efficacy; it is relatively stable to air and heat, but is hydrolysed by moisture in the presence of alkalis or strong acids into free tocopherol (DL-Tocopherol) which is readily oxydizing by losing vitamin activity, recommended pH-range: 4.0 - 8.0, sensitive to heavy metals
Solubility:	Readily soluble in all kinds of oils, freely soluble in alcohol
Microorganism:	Total viable aerobic count not more than 1000fcu/g Fungghi count not more than 100cfu/g Salmonella species not detectable in 10g Pseudomonas aeruginosa, staphylococcus aureus and escherichia coli are not detectable in 1g
Properties:	DL-alpha Tocopheryl Acetate is a high viscous liquid, but still fairly to handle at room temperature
Viscosity:	26600 mPas at 0°C 2120 mPas at 20°C 161 mPas at 60°C
Max. processing temp.:	100°C
Water hazard class:	WGK 1



Safety

Vitamin E is relatively non-toxic. Most adults can tolerate 100 to 800 mg daily without gross signs or biochemical evidence of toxicity. Large doses of over 1000 mg daily for prolonged periods have occasionally been associated with some side effects.

Requirements

Dietary recommendations for vitamin E range from 11 to 15 mg alpha tocopherol



General functions

Vitamin E is a fat-soluble vitamin that exists in eight different forms. Each form has its own biological activity. Alpha tocopherol is the most active form of vitamin E in humans.

Deficiency of vitamin E is not generally recognized as a clearly definable syndrome, but clinical signs of deficiency include reduced red blood cell half-life and neurological disturbances.

Vitamin E is a powerful biological antioxidant particularly for lipids. It protects cell membranes, here especially the susceptible poly-unsaturated fatty acids (PUFAs), and other fat-soluble parts of the body against the effects of free radicals, which are potentially damaging by-products of the body's metabolism.

Free radicals can cause cell damage that may contribute to the development of many degenerative disorders, such as coronary heart disease, Alzheimer's disease, eye cataract and cancer.

As the principal lipophilic antioxidant in the body, vitamin E plays a significant role in the prevention, as well as treatment of these disorders. When scavenging radicals vitamin E itself is transformed to a radical and can be regenerated to form the active vitamin E again by a network of other antioxidants, including vitamin C, coenzyme Q10, glutathione Peroxidase and other enzymes. But the antioxidant activity of vitamin E is not sufficient to explain the vitamin's biological activity.

Vitamin E and heart disease

Several epidemiological studies have shown a link between low vitamin E intakes and coronary heart disease. Preliminary research has led to a widely held belief that vitamin E may help prevent or delay coronary heart disease. Oxidative modification of LDL-cholesterol promotes blockages in coronary arteries that may lead to arteriosclerosis and heart attacks. Vitamin E may help avoid or delay coronary heart disease by limiting the oxidation of LDL-cholesterol. Vitamin E also may help prevent the formation of blood clots, which could lead to a heart attack.

Other actions of vitamin E

Oxidative stress is thought to be a factor in the pathogenesis of many disorders of the nervous system. Since the nervous system is rich in lipids and since vitamin E is the major lipid antioxidant, the vitamin has become attractive as a possible preventive, as well as therapeutic agent, for nervous system disorders.

There is some evidence that vitamin E supplements delay the progression of Alzheimer's disease. Furthermore it was reported to improve immune function and lung function, and to reduce oxidative damage during exercise. It may also help protect skin from ultraviolet irradiation.

The recommended dietary allowances for vitamin E is around 11 to 15 milligrams daily, which is equal to 16 to 22 IU per day for adults.

Literature:

PDR for Nutritional Supplements, 1st ed., Montvale: Medical Economics Company Inc., 2001
Pamela Mason: Dietary Supplements, second ed., London: Pharmaceutical Press, 2001
Bässler K.-H. Et al.: Vitamin Lexikon, 2nd ed. Frankfurt: Gustav Fischer, 1997

The data submitted in this publication are based on our current knowledge and experience. They do not constitute a guarantee in the legal sense of the term and, in view of the manifold factors that may affect processing and application, do not relieve those to whom we supply our products from the responsibility of carrying out their own tests and experiments. Any relevant patent rights and existing legislation and regulations must be observed.



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