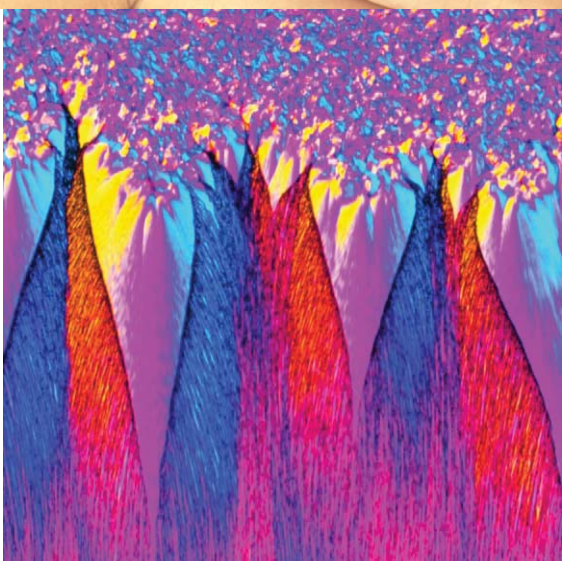
# DL-alpha TOCOPHERYL ACETATE



**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

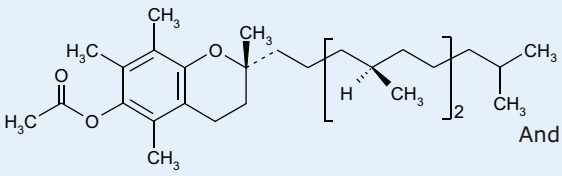
**Chemical names**
(2RS)-2,5,7,8-tetramethyl-2-[(4RS,8RS)- 4,8,12-trimethyltridecyl]-chroman-6-yl-acetate (Ph.Eur.);
(2RS,4'RS,8'RS)-6-acetoxy-2,5,7,8-tetramethyl-2-4(4',8',12'-trimethyltridecyl)-chroman (BP);
DL-6-acetoxy-2,5,7,8-tetramethyl-2(4',8',12'-trimethyltridecyl)chroman;
(2RS)-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-6-chromanylacetat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

**Offical 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 28 00
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: |  And enantiomer |
| Empirical formula: | $C_{31}H_{52}O_3$ |
| Molecular weight: | 472.7 |
| Appearance: | Clear, colourless or greenish-yellow, viscous oily liquid |
| Identification: | A: Specific optical rotation<br>B: IR Absorption Spectrophotometry<br>C: TLC test |
| Related substances: | |
| impurity A*[1] | not more than 0.5 % |
| impurity B*[2] | not more than 1.5 % |
| impurity C*[3] | not more than 0.5 % |
| impurity D* and E*[5] | not more than 1.0 % |
| any other impurity | not more than 0.25% |
| total impurities | not more than 2.5 % |
| Assay/vitamin E content: | 98,0% to 102.0%<br>(Ph. Eur.: 96,5% to 102,0%) |

*[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 Ph. Eur. Monograph for all-rac-α Tocopheryl Acetate

## Other physico-chemical properties

| | |
|---|---|
| Organic volatile impurities: | Isobutyl acetate: not more than 0.5 % |
| 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 drums
950 kg IBC.

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

## Formulating

Standardization: 1.00 mg D-alpha Tocopherol equivalent = 1.49 mg DL-alpha Tocopheryl Acetate
1mg (all-rac) DL-alpha Tocopheryl Acetate = 1.00 USP-unit
1mg 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 cosmetic oils, thus ideal mixable to the fat phase of cosmetic emulsions, freely soluble in alcohol so that supplementation of alcohol-based formulation would be possible and also useful due to the topical benefits of DL-alpha Tocopheryl Acetate

Microorganism: Total viable aerobic count not more than 1000cfu/g
Funghi 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:

Acute toxicity: different animal species showed after oral administration of high doses of vitamin E no toxic effects

Skin irritation: minimal to slight irritation under extreme conditions
Further safety information available on request

## Benefits of Topical Application

Skin penetration: DL-alpha Tocopheryl Acetate is taken up easily by the skin

Vitamin release: DL-alpha Tocopheryl Acetate is bioconverting to Tocopherol in the skin

UV exposure: DL-alpha Tocopheryl Acetate reduces UV inducted lipid peroxidation

Prevention: assists wound healing, exhibits anti-inflammatory activity, protects skin cells from UV damage, protects cells from environmental pollutants

Excerpt from data sheets for evaluation of active ingredients in cosmetics, namely Vitamin E and its esters, published by Gesellschaft Deutscher Chemiker GDCH (Society of German Chemists), workgroup 'cosmetics'. Translated from German:

".....Application as an active agent for cosmetics
In particular, Tocopherol esters are used (in cosmetics), of which Tocopheryl Acetate is the leading product. For cosmetological effects on skin, a dosage of 30 mg to 50 mg per day will be required. Following cosmetological effects are described: smoothing and improvements to the skin, relief enhancement of epithelization of skin, improvement of the water binding properties of the keratenized surface, scanvanges free radicals, reduces the activity of the ornithine carboxylase stimulation of repair mechanism of skin, protects against UV light."

Recommended concentration: 0.1% to 5.0%

## Evaluation of promoting a significant efficacy

If claims are made f.i. "for the skin" or "care effects", in this case general expectation is a content of more than 0.2%, because it should exceed the efficacy of just an antioxidative dosage.

## Evaluation of statements with extraordinary promotional promises

If terms like "enriched", "fortification", "special product" or similar striking facts are used, contents of more than 0.6% are expected.

## Evaluation of promoting a significant efficacy

| **Cosmetic effect** | **Contents** |
|---|---|
| Skin care | 0.5% up to 5% |
| Body lotion | 0.5% up to 2% |
| Foam bath | 0.5% up to 3% |
| Cream bath | 1% up to 3% |
| Lipstick | 1.5% |
| Sun lipstick | 1% up to 5% |
| Sun care products | 1% up to 5% |
| After sun products | 1% up to 5% |
| Nail care products | 1% |
| Hair care | 0.1% up to 5% |
| Rinse-off products | 0.5% up to 1% |
| Deep conditioner | 0.2% up to 0.5% |
| Hair tonic | 0.2% up to 0.5% |
| Shampoo | 0.1% up to 5% |
| Hair repair | up to 5% |
| Conditioner (rinse off) | 1% up to 5% |
| Conditioner (leave on) | 0.1% up to 0.5% |
| Styling foam | 0.1% up to 0.5% |

**Literature:**
for cited literature backing the claims please refer to the GDCH date sheet "vitamin E and its esters"



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06/11