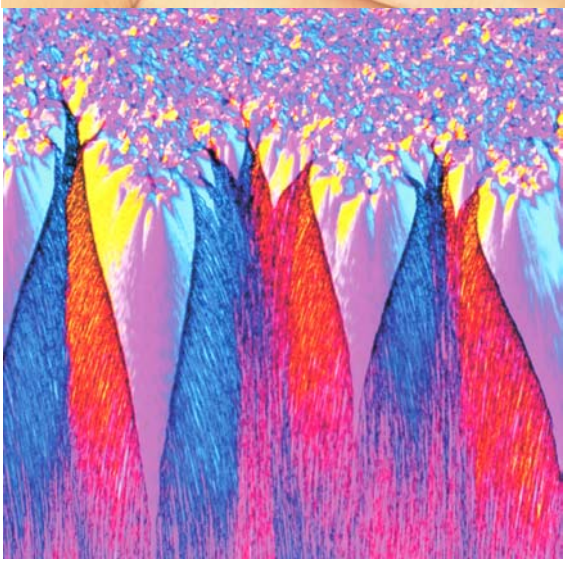


Definition
Acetic Acid Ester of all-racemic (dl) alpha-Tocopherol, belonging to the group of oil-soluble Vitamins, Universal Vitamin E-standard (1mg=1I U)

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
EEC-No.: E 307
CN-Code: 2936 28 00
Vitamin E and its derivatives

dl-alpha-TOCOPHERYL ACETATE

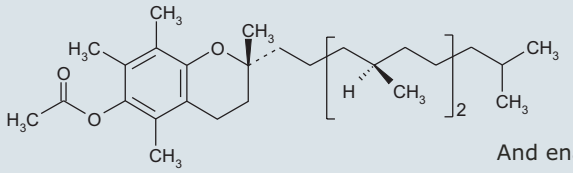
Producer: Adisseo
92164 Antony, France

ADISSEO

DAIICHI FINE CHEMICAL EUROPE GMBH

TÜV CERT DFE
DIN EN ISO 9001:2000

SPECIFICATION (Ph. Eur.)

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:	A clear, slightly greenish yellow, viscous, oily liquid
Solubility:	freely soluble in acetone, in ethanol and in fatty oils, practically insoluble in water
Identification:	A: Specific optical rotation B: IR Absorption Spectrophotometry 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 %
any other impurity	not more than 0.25 %
total	not more than 2.5 %
Assay/vitamin E content:	not less than 96.5 0% and not more than the equivalent of 101,0%

*[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-α-tocopherol

Other physico-chemical properties

Relative Density:	0.95 - 0.97g/cm^3 at 20°C
Flash-point:	210°C
Absorbance in ethanol:	42.0 - 45.0 (284nm) 7.0 - 9.0 (254nm)
Volatile organic impurities*:	conforms USP
Refractive Index*:	1.494 - 1.498
Lead*:	less than 4ppm
Manufacturing route:	pure synthetical synthesis route, not involving any materials of animal origin or gene-technology
Status:	Product complies with relevant chapters, annexes and quality-specifications of the European pharma-, cosmetic- and food-regulations

*These data result from careful quality monitoring of representative samples and does not constitute a guaranty per batch at all!

Storage and packaging

Storage:	Protect against heat, humidity and light keep in an inert environment (store only under N-blanket)
Standard-Packaging:	Metal drums with 5 kg, 25 kg or 200 kg net and Schütz-Container 950 kg net, other packaging units on special request
Expiry-Date:	In unopened original packaging and under adequate storage-conditions minimum 2 years following production date

Formulating

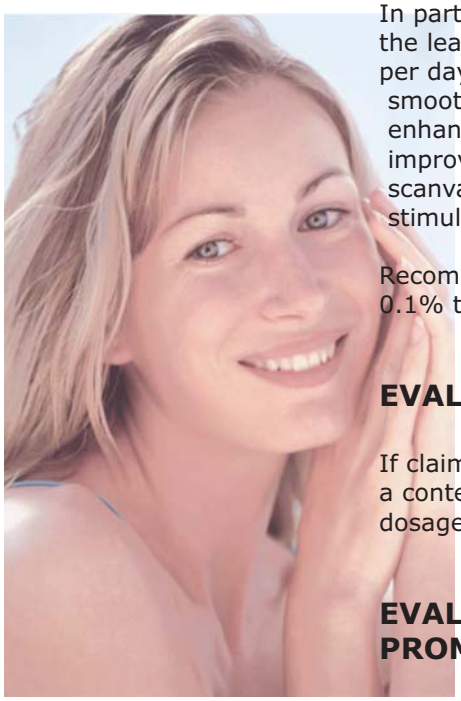
Standardization:	1.00 d-alpha-tocopherol equivalent = 1.49 mg dl-alpha-Tocopheryl 1mg (all-rac) dl-alpha-Tocopheryl Acetate = 1.00 USP-unit 1mg dl-alpha-Tocopheryl Acetate = 1.00 IU (international Unit) Vitamin E
Stability:	dl-alpha-Tocopheryl-Acetate is regarded as one of the more stable vitamins, that 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 supple-mentation of alcohol-based formulation would be possible and also useful due to the topical benefits of dl-alpha-Tocopheryl-Acetate
Microorganism:	Bacteria-count not more than 100/g Fungi not more than 10/g pathol. Causative organism like pseudomonas aeruginosa staphylococcus aureus, candida albicans, escherichia coli are not traceable
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
Relative density:	0.95 - 0.97 (at 20°C)
Max. processing temp.:	100°C
Water-hazard class:	WGK 1

Safety:

Acute toxicity:	different animal species showed after oral admini-stration 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 Topiocal 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 and
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 (3)*: 0.1% to 1.0%
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	Active ingredient
Care and protection	up to 5%	Vitamin E (4)*
Protection and care	up to 10%	
Dermatological application in special products	up to 25%	
Determination of cell revitalisation	from 2.5%	Vitamin E (2)*
Moisturiser	2% to 5%	Vitamin E acetate (5)*
Sun protection agent	3% to 5%	
Anti-ageing cream	3% to 5%	
After-sun products	1% to 5%	
Aftershave lotion	0.3%	
Day cream	0.5% to 2%	
Night cream	0.5% to 2%	
Body lotion	0.5% to 2%	
Bath gel	2% to 5%	
Cell revitalisation	2.5%	Vitamin E acetate (6)*
Care and protection	5%	Vitamin E acetate (7)*
Hair conditioner	2%	
Skin care products	2% to 5%	Vitamin E acetate (8)*
Skin care products	5% to 8%	
Special skin care products	over 8%	

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

DAIICHI FINE CHEMICAL EUROPE GMBH

Immermannstr. 50-52
40210 Düsseldorf / Germany

Tel: 0049 (0)211 - 172 52 0
Fax: 0049 (0)211 - 172 52 99

E-mail: info@daiichi.de
Homepage: www.daiichi.de

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