

Vitapherole® E-1000 Acetate Non GMO
(d-alpha tocopheryl acetate)**Names**

Chemical name: d-alpha tocopheryl acetate. 2R, 4'R, 8'R-alpha-tocopheryl acetate
Vitamin E Acetate
INCI name: tocopheryl acetate

Identification

<u>Name</u>	<u>Empirical formula</u>	<u>Molecular weight</u>	<u>CAS</u>
d-alpha tocopheryl acetate	C ₃₁ H ₅₂ O ₃	473	58-95-7

Standards

This product complies with current EP and USP-NF standards, FCC and Regulation (EC) N° 852/2004. Kosher ("Circle U") and Halal certified. Produced under UNE EN ISO 9001: 2008 standard. Non GMO (IP). It is not subjected to be labelled under Regulations (EU) 1829/2003 and 1830/2003. This product does not contain allergens according to Regulation (EU) N°1169/2011 so; it is not required labelling declaration as being potential allergen. d-alpha tocopheryl acetate is generally recognized as safe (GRAS) by FDA (21 CFR Part 182 Sec. 182.8892).

Ingredients/Composition

GC method according to IT-02-L

- D-alpha Tocopheryl acetate: 735 mg/g min. (73.5 %) min.
- Vegetable oil (sunflower): 265 mg/g max. (26.5 %) max.

Quality Control Assay

(Parameters analyzed per batch)

Appearance:	Clear, pale yellow viscous oil
Taste:	Mild, characteristic
Odour:	Little to none
Colour:	Max. 8 Gardner Units
Viscosity (60°C):	90– 100 cP
Specific gravity/Density (25°C):	0.93 – 0.96g/cm ³
Potency:	1000 I.U/g (min)
Acidity:	<0.35 ml KOH 0.1N /g (According to EP, USP and ISO 660:2009)
Benzo (a) pyrene:	< 2 ppb (As per EC Regulation (EU) 835/2011)
Sum of Benzo(a)pyrene, Benzo(a)anthracene, Benzo(b)fluoranthene and Chrysene:	< 10 ppb (As per EC Regulation (EU) 835/2011)

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(Parameters analyzed periodically based on statistical data)

Specific rotation: $(\alpha)_D^{25}$. Min. + 24° (for 100% concentration) (As per USP)

Heavy metals: Pb: <0.1ppm Hg:<0.1ppm Cd: <1ppm As: <1ppm
(As per Commission Regulation (EC) N° 629/2008, amending Regulation (EC) N° 1881/2006)

Microbiological tests: (In compliance with EP and RD 3177/83)	<i>E. Coli:</i>	None cfu/g
	<i>Salmonella:</i>	None cfu/25g
	<i>Listeria Monocytogenes:</i>	None cfu/10 g
	<i>Shigella:</i>	None cfu/10 g
	<i>Clostridium Perfringens:</i>	None cfu/g
	<i>Staphylococcus Aureus:</i>	None cfu/g
	<i>Enterobacteriaceae:</i>	max 100 cfu/g
	<i>Total Aerobic Count:</i>	max 1000 cfu/g
	<i>Yeast & Moulds:</i>	max 100 cfu/g

Residual solvents: In compliance with limits established in EP and USP for Class I solvents. This product meets as well Directive 2009/32/EC.

Dioxins:	- Sum of dioxins (WHO-PCDD/F-TEQ)	0,75 pg/g fat
	- Sum of dioxins and dioxin-like PCBs (WHO-PCDD/F-PCB-TEQ)	1, 25 pg/g fat
	- Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180 (ICES – 6)	40 ng/g fat

(In compliance with Commission Regulation (EU) N° 1259/2011)

Pesticides: In compliance with Regulation (EC) N° 396/2005, amending Council Directive 91/414/EEC, and according to current European Pharmacopoeia (EP).

Properties and Conditions

Solubility: Insoluble in water. Soluble in ethanol, animal fats and vegetable oils, essential and mineral oils. Miscible with organic solvents.

Stability: Unstable to light, heat, alkali and oxidizing conditions.

Storage: Ambient temperature. Nitrogen blanketing and protection from light, moisture and air. Store in tightly closed containers.

Shelf life: 48 months from packaging date (unopened).

Packaging: 20 and 190 kg containers are supplied for this product.
(In compliance with Commission Regulation (EU) N° 10/2011 and FDA 21 CFR)

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Labelling: All products produced using “Vitapherole® E-1000 acetate Non GMO” may be labelled as “natural source Vitamin E”.

The product is in compliance with Directive 2000/13/EC regarding labelling of foodstuffs and with Regulation (EC) N° 1223/2009 on cosmetic products (Art.19 Labelling).

Uses: “Vitapherole® E-1000 acetate Non GMO” is a natural antioxidant widely used in food and cosmetic industries to avoid the negative effects of oxidation.

This product may be added (as a Vitamin) to foods and can be used in the manufacturing of food supplements (mainly soft gelatine capsules) according to Commission Regulation (EC) N° 1170/2009 and cosmetics as per Regulation (EC) N° 1223/2009.

This product has not been irradiated at any point during the manufacturing process.

Other information

All orders and samples requested will be sent together with an Analysis Certificate and Material Safety Data Sheet. Contact us through our fax: +34 925 851021; tel: +34 925 851013; e-mail: quality@vitaenaturals.com or through our web-site at: www.vitaenaturals.com and your request will be attended to by our local representative.

All information contained here is intended to be accurate. Anyway, this document is provided for your guidance only. We recommend testing the product for your particular purpose, prior to be used in the industrial process.