

## Vitapherole® E-1300 Non GMO (d-alpha tocopherol)

### Names

Chemical name: d-alpha tocopherol. Vitamin E. 2R, 4'R, 8'R-alpha-tocopherol  
 INCI names: Tocopherol, Helianthus Annuus Seed Oil

### Identification

<u>Name</u>	<u>Empirical formula</u>	<u>Molecular weight</u>	<u>CAS</u>
d-alpha tocopherol	C <sub>29</sub> H <sub>50</sub> O <sub>2</sub>	430.69	59-02-9

### Standards

This product complies with current EP and USP-NF standards, FCC, JECFA and Regulation (EC) N° 852/2004.

Kosher ("Circle U") and Halal certified. Produced under FSSC 22000 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 tocopherol is generally recognized as safe (GRAS) by FDA (21 CFR Part 184, Sec.184.1890).

### Ingredients/Composition

GC method according to IT-02-L

▪ <u>D-alpha Tocopherol*</u> :	873 mg/g min.	(87.3 %) min.	
	Beta-Gamma tocopherol:	0 – 10 mg/g	(0 – 1 %)
	Delta tocopherol:	0 – 2 mg/g	(0 – 0.2 %)
▪ <u>Vegetable oil (sunflower):</u>	127 mg/g max.	(12.7 %) max.	

\*Derived from soybean oil

### Quality Control Assay

*(Parameters analyzed per batch)*

<b>Appearance:</b>	Clear, from amber to reddish viscous oil
<b>Taste:</b>	Mild, characteristic
<b>Odour:</b>	Typical vegetable oil
<b>Colour:</b>	Max. 12 Gardner Units
<b>Viscosity (60°C):</b>	90– 180 cP
<b>Specific gravity/Density (25°C):</b>	0.93 – 0.95g/cm <sup>3</sup>
<b>Potency:</b>	1300 I.U/g (min)
<b>Acidity:</b>	<0.35 ml KOH 0.1N /g (According to EP, USP and ISO 660:2009)
<b>Benzo (a) pyrene:</b>	< 2 ppb (As per EC Regulation (EU) 835/2011)

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**Vitapherole® E-1300 Non GMO**  
(*d*-alpha tocopherol)

**Sum of Benzo(a)pyrene,  
Benzo(a)anthracene,  
Benzo(b)fluoranthene and Chrysene:** < 10 ppb (As per EC Regulation (EU) 835/2011)

*(Parameters analyzed periodically based on statistical data)*

**Specific rotation:** ( $\alpha$ )<sub>D</sub><sup>25</sup>. Min. + 24° (for 100% concentration) (As per USP and JECFA)

**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). It also complies with JECFA limits.

<b>Microbiological tests:</b> (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 &amp; 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.

<b>Dioxins:</b>	- <b>Sum of dioxins</b> (WHO-PCDD/F-TEQ)	0,75 pg/g fat
	- <b>Sum of dioxins and dioxin-like PCBS</b> (WHO-PCDD/F-PCB-TEQ)	1, 25 pg/g fat
	- <b>Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180</b> (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.

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**Shelf life:** 36 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)

**Labelling:** All products produced using “Vitapherole® E-1300 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-1300 Non GMO” 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.

“D-Alpha Tocopherol” is authorized as nutritional additive in feed sector (all animal species) as per Commission Regulation (EU) N° 26/2011. Therefore, this product is suitable to be used in Feed.  
Vitae Naturals is registered in the Spanish Ministry of Agriculture with registration number: αESP45000298.

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](mailto:quality@vitaenaturals.com) or through our web-site at: [www.vitaenaturals.com](http://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.***