

(DRAFT)

**Vitapherole® EP-500 Acetate WD Non GMO**  
(*d-alpha tocopheryl acetate microencapsulated WD*)**Names**

Chemical name: d-alpha tocopheryl acetate. 2R, 4'R, 8'R-alpha-tocopheryl acetate  
INCI name: d-alpha tocopheryl acetate microencapsulated WD powder.

The raw material of "Vitapherole® EP-500 acetate WD Non GMO" is the "Vitapherole® E-1000 acetate Non GMO" which specifications are available upon request.

"Vitapherole® EP-500 acetate WD Non GMO" is made by spray drying the active ingredient onto an emulsifier.

**Identification**

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

**Standards**

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

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 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: 367.7 mg/g min.
- Sunflower oil: 132.3 mg/g máx.
- Starch: 500 mg/g máx.

**Quality Control Assay**

(Parameters analyzed per batch)

<b>Appearance:</b>	Clear, white to cream fine powder
<b>Taste:</b>	Bland, characteristic
<b>Odour:</b>	Bland to none
<b>Specific gravity/Density (25°C):</b>	0.35 – 0.60 g/cm <sup>3</sup>
<b>Potency:</b>	500 I.U/g (min)
<b>Loss on drying:</b>	< 5 %
<b>Benzo (a) pyrene:</b>	< 2 ppb (As per EC Regulation (EU) 835/2011)
<b>Sum of Benzo(a)pyrene, Benzo(a)anthracene, Benzo(b)fluoranthene and Chrysene:</b>	< 10 ppb (As per EC Regulation (EU) 835/2011)

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**Vitapherole® EP-500 Acetate WD Non GMO**  
(*d-alpha tocopheryl acetate microencapsulated WD*)***(Parameters analyzed periodically based on statistical data)***

(These parameters are analyzed separately in the ingredients present in the product)

**Irradiation:** This product has not been irradiated at any point during the manufacturing process.**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).

<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:** Dispersible in water. Insoluble in vegetable oils and organic solvents.**Stability:** Unstable to alkali and acid conditions. Stable to air.**Storage:** Ambient temperature. Protection from light, moisture and air. Store in tightly closed bags.**Shelf life:** 24 months from packaging date (unopened).

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**Packaging:** 15-20 kg paper bags with interior food grade bag are supplied for this product.

**Labelling:** All products produced using “Vitapherole® EP-500 acetate WD Non GMO” may be labelled as “natural source Vitamin E”.

The product is in compliance with Directive 2000/13/EC regarding labelling of foodstuffs.

**Uses:** “Vitapherole® EP-500 acetate WD Non GMO” is a natural antioxidant widely used in food industries to avoid the negative effects of oxidation.

This product may be added to foods and can be used in the manufacturing of *food supplements* (mainly hard gel capsules and multivitamins) according to Commission Regulation (EC) N° 1170/2009.

**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.***