

**Vitapherole® EP-500/GS-ORG**  
**Suitable for Organic Food**

*(Mixed tocopherols powder - high content in RRR-alpha tocopherol)*

**Names**

Chemical name: mixed tocopherols  
Antioxidant: E-306  
INCI name: tocopherol

**General Characterization**

Vitapherole® EP-500/GS-ORG is an off white/beige free flowing granular powder. The active ingredient, alpha-tocopherol, is derived from non-GMO, IP certified sunflower oil and is produced by physical and chemical means. It is then absorbed onto silicon dioxide. It is intended for use as Vitamin E in the food and dietary supplement industry.

**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
d-beta tocopherol	C <sub>28</sub> H <sub>48</sub> O <sub>2</sub>	416.66	16698-35-4
d-gamma tocopherol	C <sub>28</sub> H <sub>48</sub> O <sub>2</sub>	416.66	54-28-4
d-delta tocopherol	C <sub>27</sub> H <sub>46</sub> O <sub>2</sub>	402.64	119-13-1

**Standards**

This product complies with current USP-NF standard, FCC, JECFA and Regulation (EC) N° 852/2004. Kosher ("Circle U") and Halal certified. Produced under UNE EN ISO 9001: 2008 and FSSC 22000 standards.

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.

Mixed tocopherols are generally recognized as safe (GRAS) by FDA (21 CFR Part 182, Sec. 182.8890 and 182.3890).

Organic attestation: This product is suitable for use under NOP Organic production.

**Ingredients/Composition**

*GC method according to IT-02-L*

- Mixed tocopherols (high content in RRR-alpha tocopherol) from sunflower: 335 mg/g min. (33.5 %) min.
 

Alpha tocopherol:	335 mg/g min. (33.5 %) min.
Beta-Gamma tocopherol:	0 – 50 mg/g (0 – 5 %)
Delta tocopherol:	0 – 25 mg/g (0 – 2.5 %)
- Silicon dioxide SiO<sub>2</sub> carrier (free flowing type) (E-551): 500 mg/g max. (50 %) max.
- Vegetable oil (sunflower): 165 mg/g max. (16.5%) max.

**Vitapherole® EP-500/GS-ORG**  
**Suitable for Organic Food***(Mixed tocopherols powder - high content in RRR-alpha tocopherol)***Quality Control Assay***(Parameters analyzed per batch)*

<b>Appearance:</b>	Off-white to beige granular 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>Acidity:</b>	< 1 ml KOH 0.1N /g (According to USP and ISO 660:2009)
<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)
<b>Loss of drying:</b>	< 5%

*(Parameters analyzed periodically based on statistical data)**(These parameters are analyzed separately in the ingredients present in the product)***Particle size:** 90% ≥ 400 µm (40 mesh)**Specific rotation (for Mixed tocopherols):** (α)<sub>D</sub><sup>25</sup>. Min. + 20° (for 100% concentration)  
(As per Commission Directive 2008/84/EC, Commission Regulation (EU) N° 231/2012 and JECFA)**Heavy metals (for Mixed tocopherols):** Pb: <0.1ppm Hg: <0.1ppm Cd: <1ppm As: <1ppm  
(As per Commission Regulation (EC) N° 629/2008, amending Regulation (EC) N° 1881/2006). Complies also with Commission Regulation (EU) N° 231/2012 and JECFA limits.**Heavy metals (for Silicon dioxide):** Pb: <5ppm Hg: <1ppm Cd: <2ppm As: <3ppm  
(As per Commission Regulation (EC) N° 231/2012)**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 &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.

**Vitapherole® EP-500/GS-ORG**  
**Suitable for Organic Food***(Mixed tocopherols powder - high content in RRR-alpha tocopherol)*

<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 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:** 12 months from packaging date (unopened).

**Packaging:** 20 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® EP-500/GS-ORG” 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/GS-ORG” is a natural antioxidant widely used in food industries to avoid the negative effects of oxidation.

“Vitapherole® EP-500/GS-ORG” is 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.

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.**