

Vitapherole® E-900 Sunflower-ORG

Suitable for Organic Food

(High content in RRR-alpha tocopherol)

Names

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

General Characterization

Vitapherole E-900Sunflower-ORG is a clear amber viscous oil containing mixed tocopherols, primarily alpha-tocopherol. It is produced from Non-GMO, IP certified sunflower oil through physical means. The mixed tocopherols are then diluted in organic sunflower oil. It is intended for use as Vitamin E/mixed tocopherol 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 ₂₉ H ₅₀ O ₂	430.69	59-02-9
d-beta tocopherol	C ₂₈ H ₄₈ O ₂	416.66	16698-35-4
d-gamma tocopherol	C ₂₈ H ₄₈ O ₂	416.66	54-28-4
d-delta tocopherol	C ₂₇ H ₄₆ O ₂	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 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.

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 to Organic Farming according to regulations (EC) N° 834/2007 and 889/2008 and NOP Organic production.

Ingredients/Composition

GC method according to IT-02-L

▪ <u>Natural Mixed Tocopherols*:</u>	604 mg/g min.	(60.4 %) min.
Alpha tocopherol:	604 mg/g min.	(60.4 %) min
Beta-Gamma tocopherol:	0 – 100 mg/g	(0 – 10 %)
Delta tocopherol:	0 – 50 mg/g	(0 – 5 %)
▪ <u>Organic vegetable oil (sunflower):</u>	396 mg/g max.	(39.6%) max.

*Derived from sunflower oil

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Quality Control Assay*(Parameters analyzed per batch)*

Appearance:	Clear, from amber to reddish viscous oil
Taste:	Mild, characteristic
Odour:	Typical vegetable oil
Colour:	Max. 14 Gardner Units
Viscosity (60°C):	90 – 180 cP
Specific gravity/Density (25°C):	0.93 – 0.95 g/cm ³
Potency:	900 I.U./g (min)
Acidity:	< 1 ml KOH 0.1N /g (According to 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)

(Parameters analyzed periodically based on statistical data)

Specific rotation: (α)_D²⁵. Min. + 20° (for 100% concentration)
(As per Commission Directive 2008/84/EC, Commission Regulation (EU) N° 231/2012 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). Complies also with Commission Regulation (EU) N° 231/2012 and JECFA limits.

Microbiological tests:	<i>E. Coli:</i>	None cfu/g
(In compliance with EP and RD 3177/83)	<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

Sulphated ashes: < 0.1%
(In compliance with Directive 2008/84/EC, Commission Regulation (EU) N° 231/2012 and JECFA)

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

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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: 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-900 sunflower-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® E-900 sunflower-ORG” is a natural antioxidant widely used in food industries to avoid the negative effects of oxidation.

This product is permitted as “food additive” under Regulation (EC) N° 1333/2008 and Commission Regulation (EU) N° 231/2012.

“Vitapherole® E-900 sunflower-ORG” may be used in the manufacturing of *food supplements* 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 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.*