

Vitapherole® T-70-S Non GMO
(Mixed tocopherols concentrate)
Names

Chemical name: Mixed Tocopherols
 Antioxidant: E-306
 INCI names: Tocopherol, Glycine Soja (Soybean) Oil

Identification

<u>Name</u>	<u>Empirical formula</u>	<u>Molecular weight</u>	<u>CAS</u>
Mixed tocopherols	Not applicable	≥ 402 – ≤ 431	1406-66-2
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 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. Mixed tocopherols are generally recognized as safe (GRAS) by FDA (21 CFR Part 182, Sec.182.8890 and 182.3890).

Ingredients/Composition

GC method according to IT-02-L

▪ <u>Natural Mixed Tocopherols*</u> :	700 mg/g min.	(70 %) min.	(100 %)
Non Alpha tocopherol:	560 mg/g min.	(56 %) min.	(80 %) min.
Alpha tocopherol:	0 – 140 mg/g	(0 – 14 %)	(0-20 %)
Beta tocopherol:	0 – 70 mg/g	(0 – 7 %)	(0-10 %)
Gamma tocopherol:	350 – 490 mg/g	(35 – 49 %)	(50-70 %)
Delta tocopherol:	70 – 210 mg/g	(7 – 21 %)	(10-30 %)
▪ <u>Vegetable oil (soybean):</u>	300 mg/g max.	(30 %) max.	

*Derived from soybean oil

Quality Control Assay

(Parameters analyzed per batch)

Appearance:	Clear, brownish red viscous oil
Taste:	Mild, characteristic
Odour:	Typical vegetable oil
Colour:	Max. 14 Gardner Units
Viscosity (60°C):	80 – 210 cP

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Page 1 of 3

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Specific gravity/Density (25°C):	0.92 – 0.96 g/cm ³
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)

(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: (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

Sulphated ashes: 0.1% max.
(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, Class II 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).

Vitapherole® T-70-S Non GMO
(Mixed tocopherols concentrate)**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) for 20 and 190 kg.
12 months from packaging date (unopened) for 10 kg.

Packaging: 10, 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® T-70-S 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® T-70-S Non GMO” is a natural antioxidant widely used in food and cosmetic industries to avoid the negative effects of oxidation.

Dosage information:

We recommend testing with several different amounts of “Vitapherole® T-70-S Non GMO” between 300 and 2000 ppm, which is equivalent to 0.03 to 0.2 % based on the fat content.

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

“Vitapherole® T-70-S Non GMO” may be used in the manufacturing of *food supplements* according to Commission Regulation (EC) N° 1170/2009 and *cosmetics* as per Regulation (EC) N° 1223/2009.

“Mixed tocopherols” is authorized as antioxidant in feed sector (all animal species) as per Commission Implementing Regulation (EU) N° 2015/1152. 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 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.