

Vitapherole® TP-350 PA Non GMO
(Mixed tocopherols concentrate powder)**Names**

Chemical name: mixed tocopherols

INCI name: tocopherol

The raw material of “Vitapherole® TP-350 PA Non GMO” is the “Vitapherole®T-70 Non GMO” which specifications are available upon request.

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

“Vitapherole® TP-350 PA Non GMO” complies with 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).

Mixed tocopherols comply with current EP, USP, FCC and JECFA.

Ingredients/Composition

GC method according to IT-02-L

- Natural Mixed Tocopherols: (50%) (Total tocopherols content: 350 mg/g min)
- Silicon dioxide (compressing type): (30%)
- Ascorbyl Palmitate (20%)

Quality Control Assay

(Parameters analyzed per batch)

Appearance:	Clear, white to cream fine powder
Taste:	Bland, characteristic
Odour:	Bland to none
Specific gravity/Density (25°C):	0.35 – 0. 60 g/cm ³
Acidity: (as mixed tocopherols)	< 0.35 ml KOH 0.1N /g (According to EP, USP and ISO 660:2009)
Loss on drying:	< 5 %

Last revision: 17.11.16. (Issue 8)

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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)

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

Particle size: D(50) = 50µm

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)

Heavy metals (for Ascorbyl palmitate): Pb: <2ppm Hg:<1ppm Cd: <1ppm As: <3ppm
(As per Commission Regulation (EU) N° 231/2012)

Heavy metals (for Silicon dioxide): Pb: <5ppm Hg:<1ppm Cd: <2ppm As: <3ppm
(As per Commission Regulation (EU) 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 & Moulds:</i>	max 100 cfu/g

Sulphated ashes (for Mixed Tocopherols and Ascorbyl palmitate): 0.1% max.
(In compliance with Directive 2008/84/EC and Commission Regulation (EU) N° 231/2012)

Residual solvents: In compliance with limits established in EP and USP for Class I 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).

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Solubility: Insoluble in water and organic solvents.

Stability: Stable to air. Unstable to alkali and acid conditions.

Storage: Ambient temperature. Protection from light, moisture and air. Store in tightly closed bags.

Shelf life: 12 months from packaging date (unopened).

Packaging: 25 kg carton drums with interior plastic bag are supplied for this product.
(Carton drum in compliance with Regulation (EC) N° 1935/2004 and Plastic bag in compliance with Regulation (EC) N° 1935/2004, Commission Directive 2002/72/EC and Commission Regulation (EC) N° 1895/2005)

Labelling: All products produced using “Vitapherole® TP-350 PA 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® TP-350 PA Non GMO” 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® TP-350 PA Non GMO” 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.