

Vitapherole® EP-700/G Acetate Non GMO (*d-alpha tocopheryl acetate powder*)

Names

Chemical name: d-alpha tocopheryl acetate. 2R, 4'R, 8'R-alpha-tocopheryl acetate

INCI name: tocopheryl acetate

The raw material of "Vitapherole® EP-700/G acetate Non GMO" is the "Vitapherole® E acetate Non GMO" which specifications are available upon request.

General Characterization

Vitapherole EP-700/G Acetate Non-GMO is an off-white/beige free flowing granular powder. The active ingredient, Vitamin E acetate is derived from non-GMO, IP certified soybean 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 tocopheryl acetate | C ₃₁ H ₅₂ O ₃ | 473 | 58-95-7 |

Standards

This product complies with current EP and USP-NF standards, FCC 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.

d-alpha tocopheryl acetate is generally recognized as safe (GRAS) by FDA (21 CFR Part 182 Sec. 182.8892).

Silicon dioxide (SiO₂) may be safely used in food as per FDA (21 CFR Part 172, Sec. 172.480)

Ingredients/Composition

GC method according to IT-02-L

- D-alpha Tocopheryl acetate*: 514.7 mg/g min.
- Vegetal (sunflower) oil: 95 mg/g min
- Silicon dioxide SiO₂ carrier (free flowing type): 390.3 mg/g max.

*Derived from soybean oil

Quality Control Assay

(Parameters analyzed per batch)

| | |
|---|------------------------------------|
| Appearance: | Off-white to beige granular powder |
| Taste: | Bland, characteristic |
| Odour: | Bland to none |
| Specific gravity/Density (25°C): | 0.50 – 0.80 g/cm ³ |

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Vitapherole® EP-700/G Acetate Non GMO

(d-alpha tocopheryl acetate powder)

| | |
|--|---|
| Potency: | 700 I.U/g (min) |
| Acidity: (as d- α -tocopheryl acetate) | < 0.35 ml KOH 0.1N /g (According to EP, USP and ISO 660:2009) |
| Loss on drying: | < 5 % |
| 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: | 90 % \geq 400 μ m (40 mesh) |
| Irradiation: | This product has not been irradiated at any point during the manufacturing process. |
| Heavy metals: (As per Commission Regulation (EC) N° 629/2008, amending Regulation (EC) N° 1881/2006. | Pb: <0.1ppm Hg:<0.1ppm Cd: <1ppm As: <1ppm |

| | | |
|---|---------------------------------|----------------|
| 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 |

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).

Vitapherole® EP-700/G Acetate Non GMO (d-alpha tocopheryl acetate powder)

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: 48 months from packaging date (unopened).

Packaging: 20 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®EP-700/G Acetate 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-700/G Acetate 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 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.