



azienda chimica e farmaceutica

## SPECIFICA TECNICA

Prodotto **VITAMINA E (DL-ALFA TOCOFEROLO) Ph.Eur.**

| SPECIFICA  | METODO | Lim. Inf. - Lim. Sup.       | u.m.    |
|--|--------|-----------------------------|---------|
| Identificazione IR                                   |        | conforme alla specifica     |         |
| Aspetto  |        | Olio viscoso giallo-marrone |         |
| Identificazione GC                                   |        | Conforme                    |         |
| Titolo Tocoferolo (Ph. Eur.)                         |        | 96,00 - 102,00              | g/100 g |
| Impurezza A  |        | $\leq 0,5$                  | %       |
| Impurezza B  |        | $\leq 1,50$                 | %       |
| Impurezza C e D                                      |        | $\leq 1,00$                 | %       |
| Ogni altra impurezza                                 |        | $\leq 0,25$                 | %       |
| Impurezze totali                                     |        | $\leq 2,50$                 | %       |
| Rotazione ottica                                     |        | -0,01 - 0,01                | °       |
| Acidità  |        | Conforme                    |         |
| Assorbanza specifica (al max. 292 nm in etanolo) (*) |        | $\geq 72 - \leq 76$         | °       |
| Indice di rifrazione (*)                             |        | $\geq 1,503 - \leq 1,507$   | °       |
| Ceneri solforiche (*)                                |        | $\leq 0,1$                  | g/100 g |
| Metalli pesanti (*)                                  |        | $\leq 10$                   | mg/Kg   |
| Nichel (*)   |        | $\leq 2$                    | mg/Kg   |
| Solventi residui (*)                                 |        | $\leq 3000$                 | mg/Kg   |
| Solventi residui (*)                                 |        | $\leq 0,5$                  | g/100 g |
| Revisione Capitolato                                 |        | 1                           |         |
| Data Approvazione                                    |        | 04/02/2016                  |         |

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati



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The composition of the is typically the following:

| Constituent (INCI Name) | CAS N°     | Target (wt %) |
|-------------------------|------------|---------------|
| Tocopherol              | 10191-41-0 | complete      |

### Compliance with European Union cosmetics legislation

We hereby confirm that the cosmetic raw material is conforms with the requirements relevant to cosmetic ingredients of the Cosmetics Regulation (EC) 1223/2009 and its amendments as currently in force.

### Manufacturing and raw materials

Chemical reaction

### Radioactive material

Based on information concerning the raw materials, production process, and equipment used radioactive material is not expected to be present and no irradiation has been used.

### Raw materials

Of mineral oil/natural gas origin

### Pesticides

Based on information concerning the raw materials, production process, and equipment used, pesticides are not likely to be present.

### Heavy metals

Heavy metals in sum (as Pb) max. 10 ppm

### Aflatoxin/Mycotoxin

ased on information concerning the raw materials, production process, and equipment use Aflatoxin/Mycotoxin are not likely to be present .

### Polycyclic aromatic hydrocarbons

Based on information concerning the raw materials, production process, and equipment used, polycyclic aromatic hydrocarbons are not likely to be present.

### Residual monomers

Not relevant

### Other impurities

Residual reactant: max 1% Tocopherol

### Allergens

- Based on information concerning the raw materials, production process, and equipment used fragrance allergens as of EU Regulation 1223/2009 Annex III, No. 67-92 are not likely to be present.
- Based on information concerning the raw materials, production process, and equipment used food allergens as of EU Directive 2000/13/EC (as amended), Annex IIIa, and Regulation (EU) 1169/2011, Annex II are not likely to be present.

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**Other data:**

UNIT: 1 mg of DL-alpha-tocopherol=0.74 D-alpha-TE = 1.10 former USP units.

**Phthalates**

Based on information concerning the raw materials, production process, and equipment used phthalates listed in EU Regulation 1223/2009 Annex II are not likely to be present.

**CMR substances**

Based on information concerning the raw materials, production process, and equipment used CMR substances according to Annex VI of the CLP Regulation (EC) 1272/2008) are not likely to be present.

**Glycol ethers**

Based on information concerning the raw materials, production process, and equipment used the following glycol ethers are not likely to be present:

Butyldiglycol (CAS No 112-34-5)

Ethyldiglycol (CAS No 111-90-0)

2-Butoxyethanol (CAS No 111-76-2)

**Nanomaterials**

Concerning new requirements for nanomaterials in cosmetic products, laid down in the Cosmetics Regulation (EC) 1223/2009, the following definition is provided in Article 2, 1 (k) of Regulation (EC) 1223/2009: 'Nanomaterial' means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm' The product is not considered as a nanomaterial under this definition.

**Microbiological information**

Based on our current knowledge of our production process, raw materials, and equipment used we do not expect microbiological contamination. Phthalates

Based on information concerning the raw materials, production process, and equipment used phthalates listed in EU Regulation 1223/2009 Annex II are not likely to be present.

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

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