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C.F. e PARTITA IVA 00098610330 CAP. SOC. EURO 2.000.000 I.V. R.I.PC 032-1483 R.D.PC 44507 MECC EXPORT PC002237

azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto VITAMINA A PALM. 1,0 MUI Ph.Eur. c/tocof

NOME INCI Retinyl Palmitate, Helianthus Annuus Seed oil

NOME INCI USA Retinyl Palmitate (and) Helianthus Annuus (Sunflower) Seed oil

CAS 79-81-2; 8001-21-6; 10191-41-0 FORMULA Retinyl Palmitate: C36H60O2

PESO MOLECOLARE 524,9 g/mol

| SPECIFICA | METODO | Lim. Inf Lim. Sup. | u.m. |
|--|--------|--------------------------------|-----------|
| Aspetto | | Olio giallo o giallo-brunastro | |
| Identificazione TLC | | Conforme | |
| Titolo | | 1,00 - 1,10 | Mio.I.U/g |
| Indice di perossidi | <=10,0 | | meqO2/Kg |
| Indice di acidità | <=2,0 | | mgKOH/g |
| Retinolo | | <=1,0 | % |
| Sostanze Correlate | | | |
| - Rapporto assorbanze A300 nm / A326 nm | | <=0,60 | |
| - Rapporto assorbanze A350 nm / A326 nm | | <=0,54 | |
| - Rapporto assorbanze A370 nm / A326 nm | | <=0,14 | |
| Metalli pesanti * | <=10 | | ppm |
| Nichel * | | <=2 | ppm |
| Solventi Residui | | | |
| - Metanolo * | | <=3.000 | ppm |
| - Eptano, Metile Acetato, Isopropanolo * | | <=5.000 | ppm |
| Revisione Capitolato | | 2 | |
| Data Approvazione | | 03/01/2017 | |

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* test è stato verificato su campioni casuali / test is verified on random samples

The product is stabilized by tocopherol (approx. 10 mg of DL-alpha-Tocopherol per Mio IU).

The product meets the specifications of the following monographs:

- "Vitamin A Concentrate (Oily Form), synthetic" of Ph. Eur.
- "Vitamin A" of USP/NF

Solubility:

Miscible with hydrocarbons, ethers, fats and oils. The solvent should contain no peroxides. Insoluble in water. It is necessary to use a solubilizer in aqueous alcoholic preparations.

- 1 International unit (IU) can be converted into weight with the following equations:
- 1 IU = 0.55 ug Vitamin A Palmitate

Stability and storage:

Vitamin A Esters are sensitive to air, light, moisture and heat. Opened original containers should be flushed with an inert gas and used up quickly. Prior to use, the product must be heated to 40°C in the unopened container and homogenized.

Declarations:

The raw materials are:

- of vegetable origin.
- derived from non-genetically modified plant.

BSE Classification:

- Of mineral oil/natural gas origin

Composition:

| Composition. | | | |
|--|------------|--|--|
| Constituent (INCI Name) | CAS N | Target (wt %) | |
| Retinyl Palmitate | 79-81-2 | 1.0 – 1.10 MioIU/g equiv. to 55-60% * | |
| Helianthus Annuus Seed Oil (EU); Helianthus Annuus (Sunflower) SeedOil | 8001-21-6 | min. 40 % | |
| Tocopherol | 10191-41-0 | ca. 1% | |

^{*} Conversion factor: 1 I.U. = 0.550 mcg retinyl palmitate

The above mentioned product is not tested with respect to natural latex.

As to the actual knowledge of our production process, raw materials and equipment used, we do not expect any natural latex and have no indication for any natural latex contained in the product.

The product conforms with the requirements relevant to cosmetic ingredients of the Cosmetics Regulation (EC) 1223/2009 and its amendments as currently in force.

The product contains Retinyl Palmitate-Retinyl Palmitate is not listed in Annex VI of the CLP Regulation (EC) 1272/2008, but is self-classified by producer as CMR Cat 1b, due to its well-known teratogenic effects. However, it is a vitamin and thus essential, and the safe use of vitamin A in cosmetics has been confirmed by authorities and organisations.

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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