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Specification

| Concerning Product: | | | |
|---|--|--|--|
| Article number | 127479NPEU3 | | |
| Trade name / designation / denomination | Vitamin A-Acetat 325 TIU, EP/ USP/ FCC Retinolacetat | | |
| CAS number | 127-47-9 | | |
| Other names / synonyms | •Retinyl acetate; •VITAMIN A ACETATE; •Vitamin A Acetate; •Vitamin A Acetate, Synthetic, Crystalline; •Vitamin A Acetate, USP; •Vitamin A acetate in gelatin, powder, 500,000 I.U./g; •Vitamin A-acetate; •acetic acid [(2E,4E,6E,8E)-3,7-dimethyl-9-(2,6,6-trimethyl- 1-cyclohexenyl)nona-2,4,6,8-tetraenyl] ester; •retinyl acetate; •trans- RETINYL ACETATE; | | |
| EC number | 204-844-2 | | |
| Customs tariff number / CN code / TARIC | 29362100 | | |
| Molecular weight [g / mol] | 328.48828 | | |
| Formula | C ₂₂ H ₃₂ O ₂ | | |

| Parameter | Specification | Unit |
|------------------------|--|-------------------|
| Organoleptic test | | |
| Appearance | free-flowing light yellow powder consisting of pa uniform size | rticles of almost |
| Physical parameter | | |
| Loss on drying | (gravimetric; 105°C) ≤ 5,0 | % |
| Bulk density | ~ 0,6 | g/ml |
| Solubility | The product can be dispersed in cold water with as low as 10°C, to form a stable milky emulsion. | |
| Identity | | |
| Assay | * 325 000 – 373 000 | IU/g |
| Impurities | | |
| Heavy Metals (as Pb) | ≤ 10 | ppm |
| Elemental Impurities | | |
| Arsenic (As) | ≤ 1 | ppm |
| Cadmium (Cd) | ≤ 1 | ppm |
| Mercury (Hg) | ≤ 0,1 | ppm |
| Lead (Pb) | ≤ 2 | ppm |
| Nutritional data | | |
| Calories | 1238 | kJ |
| Calories | 296 | kcal |
| Carbohydrates | 61,0 | g/100g |
| All Fats | 0,0 | g/100g |
| Sodium (Nutrient) | 0,0 | g/100g |
| Protein | 0,0 | g/100g |
| Sugar | 33,0 | g/100g |
| Microbiological data | | |
| Aerobic microorganisms | 5 ≤ 1000 | CFU/g |

| Escherichia Coli. | neg. in 1 g | | | |
|---|----------------------------|-------|--|--|
| Salmonella | neg. in 25 g | | | |
| Yeast and Mould | ≤ 200 | CFU/g | | |
| Particle size distribution | | | | |
| Particle size distributio | n | | | |
| Particle size distribution Particles | n 100 mesh: ≤ 15 | % | | |
| | | % | | |

Annotation:

*: (1 International Unit (IU) = 0.344 µg Vitamin A-Acetat = 0.300 Retinol Active Equivalents (RAE) = 0.300 µg Retinol Equivalents (RE))

Regulatory information:

Allergens statement: According to Annex II of Regulation (EU) No **1169/2011** of the European Parliament and of the Council of 25th October 2011 and its amendment (EU) No **78/2014** on substances or products the above mentioned product does NOT cause allergies or intolerances and does NOT contain any allergens which have to be labelled according to these regulations.

BSE/TSE statement: Risk of BSE/TSE contamination can be excluded.

GMO statement: Genetic engineering:

For the above mentioned product there is no obligation of g.m.o. labelling as defined by the Regulations (EC) No **1829/2003** and **1830/2003** of the European Parliament and the Council of 22^{nd} September 2003.

Irradiated Status: Non-irradiated

Supplemental information:

Shelf life: 24 month

Derivation: Ingredients: Sucrose, corn starch, gum arabic (acacia gum), retinyl acetate (vitamin A-acetate), DL-alpha-tocopherol, tri- calcium phosphate

The manufacturing process of active substance is synthetic. The source of formulation is synthetic, vegetable and mineral. The product does NOT contain animal ingredients.

Note: Traceability

According to Regulation (EC) No **178/2002** the traceability of the raw materials for the product is guaranteed one step backwards and of produced batches one step forward. All instructions, which are necessary to take these steps, are implemented in the Quality manual and management system according to IFS and BRC.

Storage conditions: Stored in the original unopened packaging under in a cool (8-15 $^{\circ}$ C), dry and dark place. Avoid storage > 25 $^{\circ}$ C if possible.

Complies with monographie: Retinyl acetate 325 000 IU/g (EP/ USP/ FCC), matrix of sucrose, corn starch, gum arabic (E 414), DL-alpha- tocopherol (E 307) and tricalcium phosphate (E 341), EP/USP

Packing: The primary packaging of the above mentioned product is suitable for food.

Usage: The product is suitable for a vegetarian nutrition.

The product is suitable for a vegan nutrition.

The product is suitable for lactose intolerance diet.

The product is suitable for people with coeliac disease and sprue.

The product is in compliance with Jewish dietary laws.

The product is in compliance with Islamic dietary laws.

Chemische Werke Hommel GmbH & Co.KG This document was generated electronically and is valid without signature. Waltrop. 30. Jan. 2020

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