

TECHNICAL DATA SHEET

Effective date: 11.2023
Rev.4

Vitamin A Palmitate

INFORMATION ON SUBSTANCE / MIXTURE

INCI	Retinyl palmitate, Helianthus annuus seed oil, Tocopherol
Ingredients	Vitamin A palmitate, DL-alpha tocopherol, the assay is adjusted by adding pharmaceutical grade sunflower oil.
Chemical name of active ingredients	Retinyl palmitate, all trans retinol palmitic acid ester

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Physical parameters

Appearance	Viscous liquid Occasionally difficult to dissolve crystals can be found in the product. In such cases placing the canister in a water bath at 60 °C and letting it gently warm up, with homogenisation, will enable complete dissolution of the crystals
Color	Yellow
Odor	Characteristic
Solubility	Soluble in hydrocarbons, chlorinated hydrocarbons, ether, fats and oil, insoluble in water. The solvent should not contain peroxides.
Units	1 international unit (IU)=0.550 µg vitamin A palmitate
Assay	Min. 1.0 million IU vitamin A (=300,000 RE) per gram
Retinyl palmitate	content 55.0-60.5% Ph.Eur./USP/FCC III
Sunflower oil	content 30-50% Ph.Eur
Vitamin E	content max. 2% Ph.Eur./USP/FCC/E 307

Chemical parameters

Chemical formula	C ₃₆ H ₆₀ O ₂
Molar mass	524.9 g/mol

TRANSPORT, STORAGE and SHELF LIFE

Storage conditions	As Vitamin A is sensitive to atmospheric oxygen, light, moisture and heat it should be stored in unopened packaging, in a cool (max. 15°C), dry place. At the recommended
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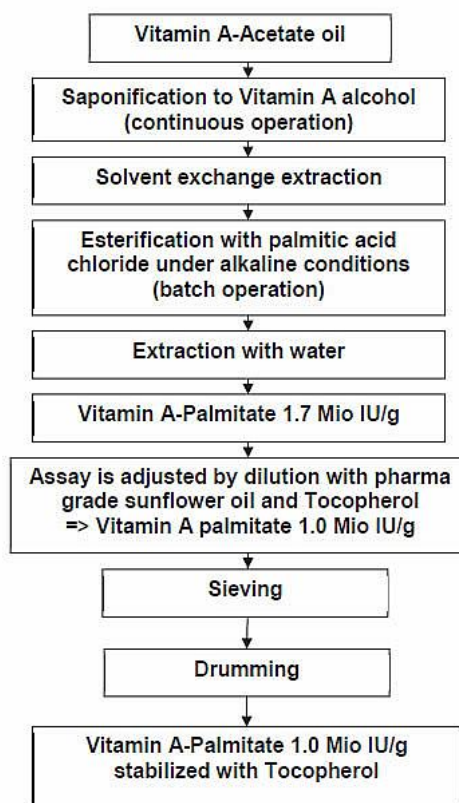
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	storage temperatures, some of the vitamin A-palmitate may crystallize. Prior to use the product must be heated to 40°C in the unopened container and homogenized.
Shelf Life	36 months, in closed packaging and the recommended conditions.
Custom tariff	-

MANUFACTURING FLOW CHART



LEGISLATION

Certification	-
Food grade	The product is suitable to be used in food in accordance with CE Reg. 1334/2008
Kosher	The product is Kosher
Monographs	The product complies with the current "vitamin A concentrate, oily form, synthetic", Ph. Eur., "vitamin A" USP, FCC III and "vitamin A concentrate oil" IP monographs

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Regulations	The product meets the regulatory requirements for vitamin A source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.
Allergen declaration	According to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products amended with Regulation (EU) 2023/1545, this material does not contain any substances listed as cosmetic allergens.
Volatile Organic Compounds (VOC)	Based on our current knowledge of our production process, raw materials and equipment used, we do not expect any of the listed solvents referenced in Annex 1 (Art. 2, a) of the Swiss Ordinance on the Incentive Tax on Volatile Organic Compounds, SR 814.018, to be present in the product at a concentration above the limit of 3 % (Limit defined in Art. 8 for tax exemption).
Microplastic	Based on information concerning the raw materials, production process and equipment used, polymers are not expected to be present neither are intentionally added in the product. Consequently, the product cannot be regarded as synthetic polymer microparticle (SPM) according to COMMISSION REGULATION (EU) 2023/2055 of 25 September 2023
Irradiation	Based on information concerning the raw materials, production process, and equipment used radioactive material is not expected to be present
GMO status	Derived from non-genetically modified plant. GMO-free (not containing genetically modified DNA)
Biodiversity related frameworks (e.g. Nagoya Protocol, CITES)	Based on our current knowledge the product and/or its components is out of scope of the access and benefit-sharing obligations laid down in the Nagoya-Protocol, as implemented by EU-Regulation 511/2014
CMR substances	May contain the following CMR substances: Contains Retinyl palmitate - Retinyl palmitate is not listed in Annex VI of the CLP Regulation (EC) 1272/2008), but is self-classified by manufacturer 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. The presence of traces of the listed CMR substances, stemming from raw materials used and/or being formed in the manufacturing process of the product in question, is not intended and is technically unavoidable. In accordance with Article 17 of the Cosmetics Regulation (EC) 1223/2009 such traces of CMR substances are accepted.
Nanomaterials	The product and/or its components is not considered to be a nanomaterial under this definition. Nanomaterials are defined in the Cosmetics Regulation (EC) No. 1223/2009 as follows: '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'

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Product-specific information on Animal Testing	For the purposes of the European Cosmetics Regulation (EC) No. 1223/2009, no animal testing has been carried out by or on behalf of manufacturer and supplier on the product/ingredients after 11th March 2009 and after 11th March, 2013 (extended deadline for animal testing for repeated dose, reproductive toxicity or toxicokinetics).
Information for Vegan Assessment	<p>General: The information in this document is provided for "Vegan" suitability assessment. Compliance with a particular "Vegan" label is unintended and responsibility of the cosmetic product manufacturer.</p> <p>Status information:</p> <p>For the purposes of manufacture the definition "animal" applied is all vertebrates and multicellular invertebrates.</p> <p>Manufacture does not involve, or have involved, the use of any animal product, by-product or ingredient.</p> <p>Cross-contamination from animal substances is excluded/minimized as far as reasonably possible.</p> <p>When applicable the use of genetically modified organisms (GMO) have not involved animal genes or animal-derived substances.</p> <p>In contrast to EU Food regulation, it is a mandatory obligation that cosmetic ingredient suppliers generate toxicological data in order to be legally compliant.</p> <p>For the purposes of chemical and cosmetic regulation the definition "animal" is according to the EU directive 2010/63 of the European Parliament and the council on the protection of animals used for scientific purposes</p>
Statement Cruelty Free INTERNATIONAL (CFI)	<p>Based on the available information it is up to the producer of the finished cosmetic product to define the suitability of the final cosmetic product against the Cruelty Free INTERNATIONAL criteria.</p> <p>For cosmetic purposes according to EC 1223/2009 no animal tests for cosmetic ingredients have been performed after the deadline March 11th 2009 and the extended deadline March 11th 2013, as this could result in a marketing ban for the final cosmetic product.</p> <p>Only active ingredients defined as chemical substances or compounds defined by its INCI or CAS number that is required to be listed on the label of the final cosmetic product (as per EC 1223/2009) will be considered.</p> <p>Reported study dates are predominantly "end of in-life phases" of the test animals</p> <p>Last animal test date (cosmetic purposes): 1988 (Phototoxicity (guinea pigs))</p> <p>Animal tests (for any purpose) after 11.03.2013 (or last animal test prior to 11.03.2013): 2005 (2. Gen, range finding)</p>
EINECS	201-228-5 232-273-9 233-466-0
CAS	79-81-2 8001-21-6 10191-41-0

DISCLAIMER

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All warranty claims in respect to the conformity of our product are subject to our General Terms and Conditions of Sale and Delivery. The data listed above reflects the results of the manufacturer or our supplier quality tests. We do not hereby make any express or implied warranty, whether for specific properties or for fitness for any particular application or purpose. All values are valid for the product when dispatched from the works. We recommend you perform your own quality and or identification checks on receipt.

ELEMENTAL