Chemical names of active ingredient
Retinyl palmitate, all-trans retinol palmitic acid ester

CAS-No. 79-81-2
EINECS-No. 201-228-5

PRD-Nos. Articles
30041040* Vitamin A-Palmitate 1.0 Mio IU/G stabilized with BHT
55799871 5 kg plastic can
55798705 25 kg plastic bucket

30041043* Vitamin A-Palmitate 1.0 Mio IU/G stabilized with Tocopherol
55856899 5 kg plastic can
55856634 25 kg plastic bucket

* The product is kosher.

Country of origin
Germany

Units
1 International Unit (IU) = 0.550 µg vitamin A-palmitate

Description
Viscous, yellow oil at room temperature. At the recommended storage temperatures, some of the vitamin A-palmitate may crystallize. The assay is adjusted by adding pharmaceutical-grade sunflower oil.

Solubility
Soluble in hydrocarbons, chlorinated hydrocarbons, ethers, fats, and oils. The solvent should not contain peroxides. Insoluble in water.

C_{36}H_{60}O_{2} Molar mass 524.9 g/mol

Specification
Assay min. 1.0 million IU vitamin A (= 300,000 RE) per gram


Unless otherwise stated, the methods of analysis can be found in the Ph. Eur.

Monographs
The product complies with the current “Vitamin A concentrate (oily form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

Regulations
The product meets the regulatory requirements for a 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.

Stability
Vitamin A-Palmitate 1.0 Mio IU/g is stabilized with approx. 10 mg t-butylhydroxytoluene (BHT, E321) or with approx. 10 mg of DL-alpha-tocopherol (E307) per 1.0 million IU. However, it may be supplied unstabilized upon request.

Stored in its unopened original packaging in a cool (8 – 15 °C), dry place, all grades of Vitamin A-Palmitate 1.0 million IU/g are stable for at least 36 months.
Storage/Handling
As vitamin A is sensitive to atmospheric oxygen, light, moisture, and heat, it should be stored in a cool, dark place in the unopened original packaging. Once opened, it is recommended to flush the packaging with an inert gas and to use the remaining contents as quickly as possible.

Prior to use or sampling, the product must be heated to 40 °C in the unopened container and homogenized.

Applications
Dietary supplements:
For preparations with a lipophilic base, e.g., soft gelatin capsules.

Sterilization of the final product is required for parenteral use. Further information can be found in the book “Functions and Applications of BASF Pharmaceutical Excipients.”

Food products:
Used for the fortification of fatty foods, such as margarine, spreads, oils, milk, and dairy products. Quantities of 3 – 9 mg (10,000 – 30,000 IU) of vitamin A, calculated as retinol, are usually added per kg of margarine. The regulations governing the use of BHT must be observed.

Cosmetics:
For use in cosmetic oils, emulsions (creams, lotions, body milk, gels, etc.), and other preparations, e.g., lipstick, masks. The maximum quantities legally permitted for use in cosmetics must be observed.

Note
Vitamin A-Palmitate 1.0 Mio IU/G in oil must be handled in accordance with the Safety Data Sheet.

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