# Vitamin A-Palmitate 1.7 Mio IU/G

## 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
30041032*	Vitamin A-Palmitate 1.7 Mio IU/G unstab. 55857270 5 kg plastic can
	55857164 25 kg plastic bucket
30041041*	Vitamin A-Palmitate 1.7 Mio IU/G stabilized with BHT 56283231 5 kg plastic can 56283178 25 kg plastic bucket
30041031*	Vitamin A-Palmitate 1.7 Mio IU/G stabilized with Tocopherol
	558002955 kg plastic can5580024225 kg plastic bucket

\* The product is kosher.

## Country of origin

Germany

## Units

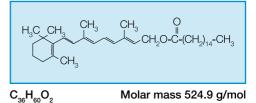
1 International Unit (IU) = 0.550 µg vitamin A-palmitate

# Description

Viscous, yellow oil at room temperature. At the recommended storage temperatures, some of the vitamin A-palmitate may crystallize.

# Solubility

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



# Specification

Assay	min. 1.7 million IU vitamin A
	(= 510,000 RE) per gram

For further information see separate document: "Standard Specification" (not for regulatory purposes) available via BASF's WorldAccount: https://worldaccount.basf.com (registered access).

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 1.7 million IU/g is unstabilized. However, it can be supplied with approx. 10 mg t-butylhydroxytoluene (BHT, E321) or with approx. 10 mg of DL-alpha-tocopherol (E307) per 1.0 million IU upon request.

Stored in its unopened original packaging in a cool (8 – 15  $^{\circ}$ C), dry place, all grades of Vitamin A-Palmitate 1.7 Mio IU/g are stable for at least 24 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 in a water bath and homogenized.

#### Applications

Dietary supplements:

For preparations with a lipophilic base, e.g., soft gelatin capsules.

#### Pharmaceutical products:

Both EU Drug Master File and US Drug Master File are available.

The product is particularly suitable for manufacturing aqueous solutions using solubilizing agents, such as Cremophor<sup>®</sup> EL or Cremophor RH 40 for oral administration, and Solutol<sup>®</sup> HS 15 for parenteral use. The chart shows the required quantity of Cremophor RH 40 for the solubilization of proportional quantities of vitamin A-palmitate.

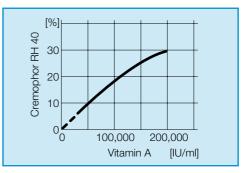
Sterilization of the final product is required for parenteral use. Further information can be found in the book "Functions and Applications of BASF Pharmaceutical Excipients."

#### Food products:

Used for the fortification of fatty foods, such as margarine, spreads, oils, milk, and dairy products. 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. A solubilizing agent is required if the product is to be used in an aqueous/alcoholic preparation. The maximum quantities legally permitted for use in cosmetics must be observed.



#### Note

Vitamin A-Palmitate 1.7 Mio IU/G must be handled in accordance with the Safety Data Sheet.

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