same color tone and the *Rf* value as those of the blue spot from retinol palmitate from the standard solution.

Purity Related substances—Retinol Acetate meets the requirements of Method 1 under the Vitamin A Assay.

Assay Proceed as directed in Method 1 under the Vitamin A Assay.

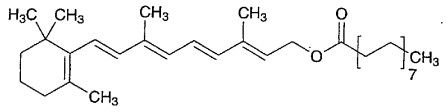
Containers and storage Containers—Tight containers.

Storage—Light-resistant, and almost well-filled, or under nitrogen atmosphere, and in a cold place.

Retinol Palmitate

Vitamin A Palmitate

パルミチン酸レチノール



$C_{36}H_{60}O_2$: 524.86

(2*E*,4*E*,6*E*,8*E*)-3,7-Dimethyl-9-(2,6,6-trimethylcyclohex-1-en-1-yl)nona-2,4,6,8-tetraen-1-yl palmitate [*79-81-2*]

Retinol Palmitate is a synthetic retinol palmitate or a synthetic retinol palmitate diluted with fixed oil, and contains not less than 1,500,000 Vitamin A Units in each gram. It may contain a suitable antioxidant.

Retinol Palmitate contains not less than 95% and not more than 105% of the labeled Units.

Description Retinol Palmitate occurs as a light yellow to yellow-red, ointment-like or an oily substance. It has a faint, characteristic odor, but has no rancid odor.

It is very soluble in 2-propanol, in chloroform, in diethyl ether and in petroleum ether, slightly soluble in ethanol (95), and practically insoluble in water.

It is affected by air and by light.

Identification **(1)** Prepare a solution of Retinol Palmitate in chloroform containing 30 Vitamin A Units per mL according to the labeled Units, pipet 1 mL of the solution, and add 3 mL of antimony (III) chloride TS: a blue color develops immediately, then fades rapidly.

(2) Proceed with Retinol Palmitate as directed in the Identification, Method 1 under the Vitamin A Assay, and perform the test: the color tone and the *Rf* value of the main spot correspond to those of the blue spot from retinol palmitate from the standard solution, and no spot appears from the sample solution having the same color tone and the *Rf* value as those of the blue spot from retinol acetate from the standard solution.

Purity Related substances—Retinol palmitate meets the requirements of Method 1 under the Vitamin A Assay.

Assay Proceed as directed in Method 1 under the Vitamin A Assay.

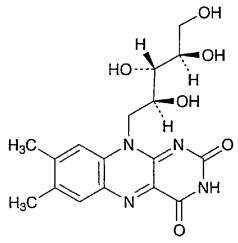
Containers and storage Containers—Tight containers.

Storage—Light-resistant, and almost well-filled, or under nitrogen atmosphere, and in a cold place.

Riboflavin

Vitamin B_2

リボフラビン



$C_{17}H_{20}N_4O_6$: 376.36

7,8-Dimethyl-10-[(2*S*,3*S*,4*R*)-2,3,4,5-tetrahydroxypentyl]-benzo[*g*]pteridine-2,4(3*H*,10*H*)-dione [*83-88-5*]

Riboflavin, when dried, contains not less than 98.0% of $C_{17}H_{20}N_4O_6$.

Description Riboflavin occurs as yellow to orange-yellow crystals. It has a slight odor.

It is very slightly soluble in water, practically insoluble in ethanol (95), in acetic acid (100), and in diethyl ether.

It dissolves in sodium hydroxide TS.

A saturated solution of Riboflavin is neutral.

It is decomposed by light.

Melting point: about 290°C (with decomposition).

Identification **(1)** A solution of Riboflavin (1 in 100,000) is light yellow-green in color and has an intense yellow-green fluorescence. The color and fluorescence of the solution disappear upon the addition of 0.02 g of sodium hydrosulfite to 5 mL of the solution, and reappear on shaking the mixture in air. This fluorescence disappears upon the addition of dilute hydrochloric acid or sodium hydroxide TS.

(2) To 10 mL of a solution of Riboflavin (1 in 100,000) placed in a glass-stoppered test tube add 1 mL of sodium hydroxide TS, and after illumination with a fluorescence lamp of 10 to 30 watts at 20-cm distance for 30 minutes between 20°C and 40°C, acidify with 0.5 mL of acetic acid (31), and shake with 5 mL of chloroform: the chloroform layer shows a yellow-green fluorescence.

(3) Determine the absorption spectrum of a solution of Riboflavin in phosphate buffer solution, pH 7.0 (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of a solution of Rivoflavin Reference Standard prepared in the same manner as the sample solution: both spectra exhibit similar intensities of absorption at the same wavelengths.

Optical rotation $[\alpha]_D^{20}$: -128 – $-142°$ Weigh accurately about 0.1 g of dried Riboflavin, dissolve in exactly 4 mL of dilute sodium hydroxide TS, add 10 mL of freshly boiled and cooled water, add exactly 4 mL of aldehyde-free alcohol while shaking, add freshly boiled and cooled water to make exactly 20 mL, and determine the rotation in a 100-mm cell within 30 minutes after preparing the solution.

Purity Lumiflavin—Shake 0.025 g of Riboflavin with 10 mL of ethanol-free chloroform for 5 minutes, and filter: the