

# Palmitic Acid

## 1 Nonproprietary Names

BP: Palmitic Acid  
PhEur: Palmitic Acid  
USP–NF: Palmitic Acid

## 2 Synonyms

Acidum palmiticum; cetylic acid; *Edenor C16 98-100*; *Emersol 140*; *Emersol 143*; *n*-hexadecoic acid; hexadecylic acid; *Hydrofol*; *Hystrene 9016*; *Industrene 4516*; *Lunac P-95*; *NAA-160*; 1-pentadecanecarboxylic acid.

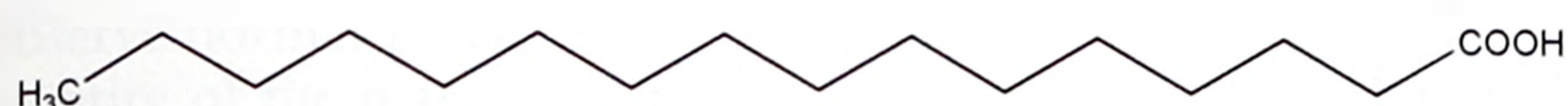
## 3 Chemical Name and CAS Registry Number

Hexadecanoic acid [57-10-3]

## 4 Empirical Formula and Molecular Weight

$C_{16}H_{32}O_2$  256.42

## 5 Structural Formula



## 6 Functional Category

Emulsifying agent; penetration enhancer; tablet and capsule lubricant.

## 7 Applications in Pharmaceutical Formulation or Technology

Palmitic acid is used in oral and topical pharmaceutical formulations as an emulsifying agent, skin penetration enhancer, and tablet and capsule lubricant.

Palmitic acid has been investigated for use in implants for sustained release of insulin in rats.<sup>(1,2)</sup>

## 8 Description

Palmitic acid occurs as white crystalline scales with a slight characteristic odor and taste.

## 9 Pharmacopeial Specifications

See Table I. See also Section 18.

**Table I:** Pharmacopeial specifications for palmitic acid.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	–
Appearance	+	–
Acidity	+	–
Acid value	216–220	216–220
Color	–	+
Freezing point	60–66°C	60–66°C
Iodine value	<1	<1
Stearic acid	<6%	≤6%
Mineral acid	–	+
Heavy metals	–	≤10 ppm
Nickel	<1 ppm	–
Assay	>92.0%	≥92.0%

## 10 Typical Properties

*Boiling point* 351–352°C; 271.5°C at 100 mmHg  
*Flash point* >110°C  
*Melting point* 63–64°C  
*Solubility* Soluble in ethanol (95%); practically insoluble in water.  
*Specific gravity* 0.849–0.851

## 11 Stability and Storage Conditions

The bulk material should be stored in a well-closed container in a cool, dry place.

## 12 Incompatibilities

Palmitic acid is incompatible with strong oxidizing agents, reducing agents, and bases.

## 13 Method of Manufacture

Palmitic acid occurs naturally in all animal fats as the glyceride, palmitin, and in palm oil partly as the glyceride and partly uncombined. Palmitic acid is most conveniently obtained from olive oil after removal of oleic acid, or from Japanese beeswax. Synthetically, palmitic acid may be prepared by heating cetyl alcohol with soda lime to 270°C or by fusing oleic acid with potassium hydrate.

## 14 Safety

Palmitic acid is used in oral and topical pharmaceutical formulations and is generally regarded as nontoxic and nonirritant at the levels employed as an excipient. However, palmitic acid is reported to be an eye and skin irritant at high levels and is poisonous by intravenous administration.

LD<sub>50</sub> (mouse, IV): 57 mg/kg<sup>(3)</sup>

LD<sub>50</sub> (rat, oral): >10000 mg/kg

## 15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. When palmitic acid is heated to decomposition, carbon dioxide and carbon monoxide are formed. Lab coat, gloves, dust respirator and safety glasses are recommended.

## 16 Regulatory Status

GRAS listed. Included in the FDA Inactive Ingredients Database (oral tablets). Included in nonparenteral medicines licensed in the UK. Included in the Canadian Natural Health Ingredients Database.

## 17 Related Substances

Lauric acid; myristic acid; palmitin; sodium palmitate; stearic acid.

### Palmitin

*Empirical formula*  $C_{51}H_{98}O_6$

*Molecular weight* 807.29

*CAS number* [555-44-2]

*Refractive index*  $n_D^{25} = 1.4381$

*Specific gravity* 0.886

*Solubility* Soluble in benzene, chloroform, and ether; practically insoluble in ethanol (95%) and in water.