

Stearic Acid

1 Nonproprietary Names

BP: Stearic acid
JP: Stearic acid
PhEur: Acidum stearicum
USPNF: Stearic acid

2 Synonyms

Crodacid; E570; *Emersol*; *Hystrene*; *Industrene*; *Kortacid* 1895; *Pristerene*.

3 Chemical Name and CAS Registry Number

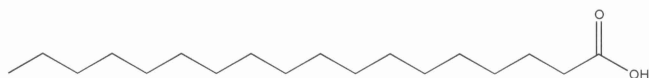
Octadecanoic acid [57-11-4]

4 Empirical Formula Molecular Weight

$C_{18}H_{36}O_2$ 284.47 (for pure material)

The USPNF 20 describe stearic acid as a mixture of stearic acid ($C_{18}H_{36}O_2$) and palmitic acid ($C_{16}H_{32}O_2$). In the USPNF 20, the content of stearic acid is not less than 40.0% and the sum of the two acids is not less than 90.0%. The USPNF 20 also contains a monograph for purified stearic acid; see Section 17. The PhEur 2002 contains a single monograph for stearic acid but defines stearic acid 50, stearic acid 70, and stearic acid 95 as containing specific amounts of stearic acid ($C_{18}H_{36}O_2$); see Section 9.

5 Structural Formula



6 Functional Category

Emulsifying agent; solubilizing agent; tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Stearic acid is widely used in oral and topical pharmaceutical formulations. It is mainly used in oral formulations as a tablet and capsule lubricant,⁽¹⁻³⁾ see Table I, although it may also be used as a binder⁽⁴⁾ or in combination with shellac as a tablet coating. It has also been suggested that stearic acid may be used as a sustained-release drug carrier.⁽⁵⁾

In topical formulations, stearic acid is used as an emulsifying and solubilizing agent. When partially neutralized with alkalis or triethanolamine, stearic acid is used in the preparation of creams.^(6,7) The partially neutralized stearic acid forms a creamy base when mixed with 5–15 times its own weight of aqueous liquid; the appearance and plasticity of the cream being determined by the proportion of alkali used.

Stearic acid is used as the hardening agent in glycerin suppositories.

Stearic acid is also widely used in cosmetics and food products.

SEM: 1

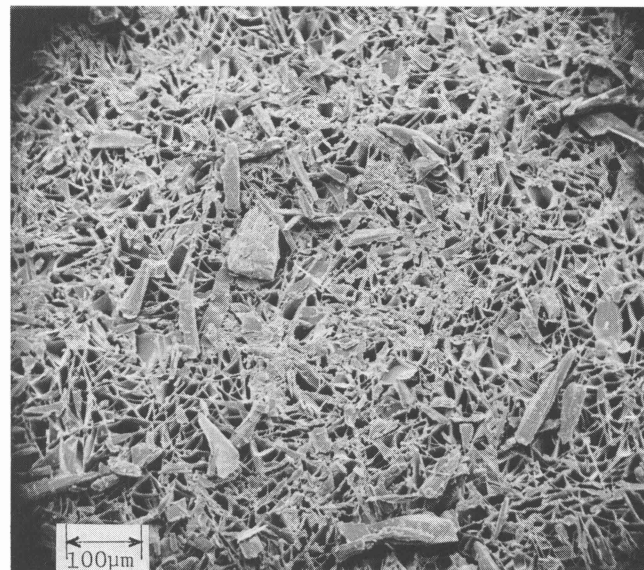
Excipient: Stearic acid, 95% (*Emersol* 153)

Manufacturer: Emery Industries

Lot No.: 18895

Magnification: 120 ×

Voltage: 10 kV



SEM: 2

Excipient: Stearic acid, food grade (*Emersol* 6332)

Manufacturer: Emery Industries

Lot No.: 18895

Magnification: 120 ×

Voltage: 10 kV

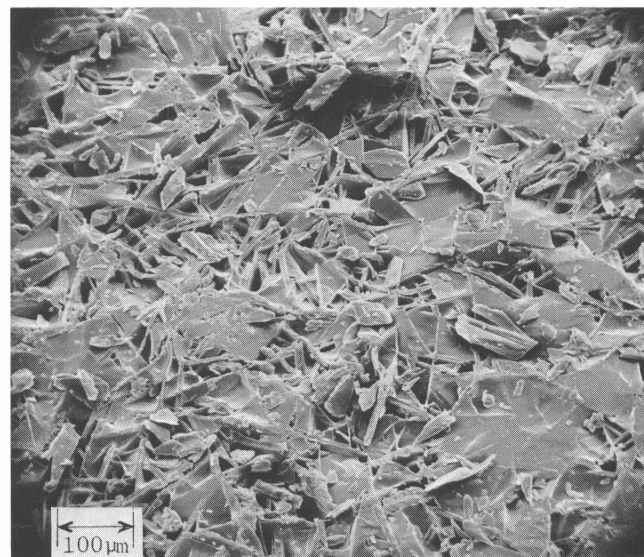


Table I: Uses of stearic acid.

Use	Concentration (%)
Ointments and creams	1–20
Tablet lubricant	1–3

8 Description

Stearic acid is a hard, white or faintly yellow-colored, somewhat glossy, crystalline solid or a white or yellowish white powder. It has a slight odor and taste suggesting tallow.

See also Section 13.

9 Pharmacopeial Specifications

See Table II.

Table II: Pharmacopeial specifications for stearic acid.

Test	JP 2001	PhEur 2002 (Suppl 4.1)	USPNF 20
Acidity	—	+	—
Acid value	194–210	194–212	—
Appearance	—	+	—
Characters	—	+	—
Content of stearic acid	—	—	≥40.0%
Stearic acid 50	—	40–60%	—
Stearic acid 70	—	60–80%	—
Stearic acid 95	—	≥90.0%	—
Content of stearic and palmitic acids	—	—	≥90.0%
Stearic acid 50	—	≥90.0%	—
Stearic acid 70	—	≥90.0%	—
Stearic acid 95	—	≥96.0%	—
Congeaing temperature	56.0–72.0°C	—	≥54°C
Freezing point	—	+	—
Stearic acid 50	—	53–59°C	—
Stearic acid 70	—	57–64°C	—
Stearic acid 95	—	64–69°C	—
Iodine value	≤4.0	+	≤4.0
Stearic acid 50	—	≤4.0%	—
Stearic acid 70	—	≤4.0%	—
Stearic acid 95	—	≤1.5%	—
Nickel	—	≤1 ppm	—
Residue on ignition	≤0.1%	—	≤0.1%
Heavy metals	≤20 ppm	—	≤0.001%
Neutral fat or paraffin	+	—	+
Mineral acid	+	—	+
Organic volatile impurities	—	—	+

10 Typical Properties

Acid value: 200–212

Density (bulk): ≈0.537 g/cm³

Density (tapped): 0.571 g/cm³

Density (true): 0.980 g/cm³

Melting point: ≥54°C

Moisture content: contains practically no water.

Saponification value: 200–220

Solubility: freely soluble in benzene, carbon tetrachloride, chloroform, and ether; soluble in ethanol, hexane, and propylene glycol; practically insoluble in water.

Specific surface area: 0.51–0.53 m²/g

See also Section 17 and Table III.

11 Stability and Storage Conditions

Stearic acid is a stable material; an antioxidant may also be added to it; see Section 13. The bulk material should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Stearic acid is incompatible with most metal hydroxides and may be incompatible with oxidizing agents.

Insoluble stearates are formed with many metals; ointment bases made with stearic acid may show evidence of drying out or lumpiness due to such a reaction when compounded with zinc or calcium salts.

A number of differential scanning calorimetry studies have investigated the compatibility of stearic acid with drugs. Although such laboratory studies have suggested incompatibilities, e.g., with naproxen,⁽⁸⁾ they may not necessarily be applicable to formulated products.

Stearic acid has been reported to cause pitting in the film coating of tablets coated using an aqueous film-coating technique; the pitting was found to be a function of the melting point of the stearic acid.⁽⁹⁾

13 Method of Manufacture

Stearic acid is manufactured by hydrolysis of fat by continuous exposure to a countercurrent stream of high-temperature water and fat in a high-pressure chamber. The resultant mixture is purified by vacuum steam distillation and the distillates are then separated using selective solvents.

Stearic acid may also be manufactured by the hydrogenation of cottonseed and other vegetable oils; by the hydrogenation and subsequent saponification of olein followed by recrystallization from alcohol; and from edible fats and oils by boiling with sodium hydroxide, separating any glycerin, and decomposing the resulting soap with sulfuric or hydrochloric acid. The stearic acid is then subsequently separated from any oleic acid by cold expression.

Stearic acid is derived from edible fat sources unless it is intended for external use, in which case nonedible fat sources may be used. Stearic acid may contain a suitable antioxidant such as 0.005% w/w butylated hydroxytoluene.

14 Safety

Stearic acid is widely used in oral and topical pharmaceutical formulations; it is also used in cosmetics and food products. Stearic acid is generally regarded as a nontoxic and nonirritant material. However, consumption of excessive amounts may be harmful.

LD₅₀ (mouse, IV): 23 mg/kg⁽¹⁰⁾

LD₅₀ (rat, IV): 21.5 mg/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Stearic acid dust may be irritant to the skin, eyes, and mucous membranes. Eye protection, gloves, and a dust respirator are recommended. Stearic acid is combustible.

Table III: Specifications of different stearic acid grades.

Product	Stearic acid content (%)	Melting range (°C)	Acid value	Iodine value	Saponification value	Unsaponifiable matter (%)
Hystrene 5016	44	54.5–56.5	206–210	≤0.5	206–211	≤0.2
Hystrene 7018	68.5	61.0–62.5	200–205	≤0.5	200–206	≤0.2
Hystrene 9718	90	66.5–68.0	196–201	≤0.8	196–202	≤0.3
Industrene 7018	65	58.0–62.0	200–207	≤1.5	200–208	≤0.5
Industrene 8718	87	64.5–67.5	196–201	≤2.0	196–202	≤1.5

16 Regulatory Status

GRAS listed. Accepted as a food additive in Europe (fatty acids). Included in the FDA Inactive Ingredients Guide (sublingual tablets; oral capsules, solutions, suspensions, and tablets; topical and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

Calcium stearate; magnesium stearate; palmitic acid; purified stearic acid; zinc stearate.

Palmitic acid

Empirical formula: $C_{16}H_{32}O_2$

Molecular weight: 256.42

CAS number: [57-10-3]

Synonyms: cetylic acid; hexadecanoic acid; hexadecylic acid.

Appearance: the pure material is a white, crystalline powder.

Boiling point: 215°C

Density: 0.853 g/cm³ at 62°C

Melting point: 63–64°C

Refractive index: $n_D^{80} = 1.4273$

Solubility: freely soluble in chloroform, ether, propan-2-ol, and hot ethanol (95%); sparingly soluble in ethanol (95%); practically insoluble in water.

Comments: the EINECS number for palmitic acid is 200-312-9.

Purified stearic acid

Empirical formula: $C_{18}H_{36}O_2$

Molecular weight: 284.47

CAS number: [57-11-4]

Synonyms: octadecanoic acid.

Acid value: 195–200

Boiling point: 361°C

Density: 0.847 g/cm³ at 70°C

Flash point: 196°C

Iodine number: ≤1.5

Melting point: 66–69°C

Refractive index: $n_D^{80} = 1.4299$

Solubility: soluble 1 in 5 parts benzene, 1 in 6 parts carbon tetrachloride, 1 in 2 parts chloroform, 1 in 15 parts ethanol, 1 in 3 parts ether; practically insoluble in water.

Vapor density (relative): 9.80 (air = 1)

Comments: purified stearic acid contains not less than 96.0% of stearic and palmitic acid, of which stearic acid constitutes not less than 90.0% of the total.

18 Comments

A wide range of different grades of stearic acid are commercially available that have varying chemical compositions and hence different physical and chemical properties; see Table III.⁽¹¹⁾

The EINECS number for stearic acid is 200-313-4.

19 Specific References

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20 General References

- Allen LV. Featured excipient: capsule and tablet lubricants. *Int J Pharm Compound* 2000; 4(5): 390–392, 404–405.
- Pilpel N. Metal stearates in pharmaceuticals and cosmetics. *Manuf Chem Aerosol News* 1971; 42(10): 37–40.

21 Author

LV Allen.

22 Date of Revision

15 October 2002.