Sodium Stearate

1 Nonproprietary Names

BP: Sodium Stearate
PhEur: Sodium Stearate
USP–NF: Sodium Stearate

2 Synonyms

Kemilub ES; natrii stearas; octadecanoic acid, sodium salt; *Prodhygine*; stearic acid, sodium salt; *STELLIESTERS SE 5S*.

3 Chemical Name and CAS Registry Number

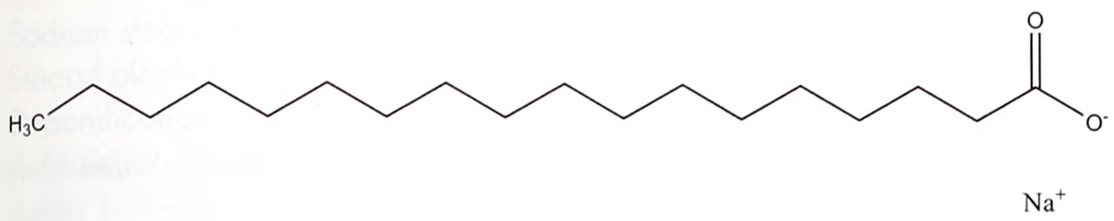
Sodium octadecanoate [822-16-2]

4 Empirical Formula and Molecular Weight

$C_{18}H_{35}NaO_2$ 306.5

The USP 40–NF 35 S1 describes sodium stearate as a mixture of sodium stearate and sodium palmitate, which together constitute not less than 90% of the total content. Sodium stearate contains small amounts of the sodium salts of other fatty acids.

5 Structural Formula



6 Functional Category

Emulsifying agent; gelling agent; glidant; modified-release agent; stiffening agent; tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Sodium stearate is used as an emulsifying and stiffening agent in a variety of topical creams[1] and rectal preparations (Glycerin Suppositories USP). It is used as a tablet and capsule lubricant in immediate-release tablets and gastro-resistant capsules both containing omeprazole. It is also used as a glidant and modified-release agent in tablets. It is used in the preparation of microemulsions.[2]

Medicated solidified sodium stearate sticks containing vitamins, fungicides, and local anesthetics have been extensively studied for their physical[3] and rheological[4] properties, stability,[5] and biological activity *in vitro* and in animals.[6] The stick dosage form proved as effective as the ointment dosage form, and showed good stability over an 18-month period.

Sodium stearate is used as a gelling agent in deodorant sticks,[7,8] and in cosmetics, shampoos, and bubble baths.

8 Description

Sodium stearate occurs as a white or yellowish fine powder, greasy to the touch with a slight, tallow-like odor.

9 Pharmacopeial Specifications

See Table I.

10 Typical Properties

Boiling point 359.4°C at 760 mmHg.
Flash point 162.4°C
Melting point 205–255°C

Table I: Pharmacopeial specifications for sodium stearate.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	—
Freezing point/solidification temperature	≥ 53°C	—
Acid value	195–210	196–211
Iodine value	—	≤4.0
Loss on drying	≤ 5%	≤ 5.0%
Acidity	+	+
Chlorides	≤ 0.2%	—
Sulfates	≤ 0.3%	—
Nickel	≤ 5 ppm	—
Microbial contamination		
Aerobic microbial count	10^3 cfu/g	—
Yeasts and molds	10^2 cfu/g	—
Alcohol-insoluble substances	—	+
Assay		
Sodium	7.4–8.5%	—
Stearic acid	≥ 40%	≥ 40%
Sum of stearic and palmitic acids	≥ 90%	≥ 90%

pH 10–11 for a 5% aqueous solution.
Solubility Slightly soluble in water, glycols, and ethanol (96%) at room temperature but readily dissolves on heating.
Specific gravity 1.02

11 Stability and Storage Conditions

Store in a well-closed container in a cool, dry place, protected from light. Keep away from sources of ignition.

12 Incompatibilities

Sodium stearate is incompatible with strong acids and oxidizing agents.

13 Method of Manufacture

Sodium stearate is prepared by reacting stearic acid with an equimolar portion of sodium hydroxide.[9]

14 Safety

Sodium stearate is generally nonirritating to skin although irritation has been reported after prolonged contact.[10] Ingestion may cause nausea, vomiting, and diarrhea. Momentary eye irritation is common. Irritant to respiratory tract and occupational asthma has been reported.[10]

LD_{50} (rabbit, skin): > 3 g/kg[11]
LD_{50} (rat, oral): > 5 g/kg[11]
LD_{Lo} (dog, IV): 0.01 g/kg[11–13]

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. When heated to decomposition, sodium stearate emits toxic and flammable fumes.

Eye protection and gloves are recommended. Sodium stearate may be harmful on inhalation and should be used in a well-ventilated environment; a respirator is recommended. In the US, the OSHA limit is 15 mg/m^3 for total dust for sodium stearate.[13] The