Sodium Stearyl Fumarate

1 Nonproprietary Names

BP: Sodium stearyl fumarate
PhEur: Natrii stearylis fumaras
USPNF: Sodium stearyl fumarate

2 Synonyms

Fumaric acid, octadecyl ester, sodium salt; *Pruv*; sodium monostearyl fumarate.

3 Chemical Name and CAS Registry Number

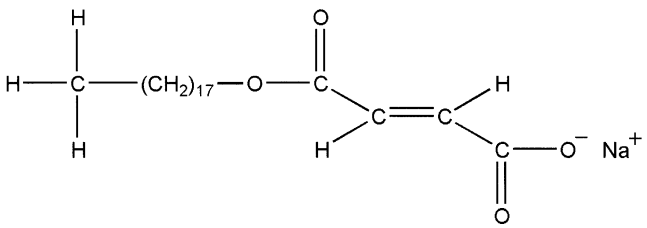
2-Butenedioic acid , monooctadecyl ester, sodium salt [4070-80-8]

4 Empirical Formula and Molecular Weight

$C_{22}H_{39}NaO_4$

390.5

5 Structural Formula



6 Functional Category

Tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Sodium stearyl fumarate is used as a lubricant in capsule and tablet formulations at 0.5–2.0% w/w concentration.[1–9] It is also used in certain food applications; *see* Section 16.

8 Description

Sodium stearyl fumarate is a fine, white powder with agglomerates of flat, circular-shaped particles.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for sodium stearyl fumarate.

Test	PhEur 2002	USPNF 20
Identification	+	+
Characters	+	—
Water	⩽5.0%	⩽5.0%
Lead	—	⩽0.001%
Heavy metals	—	⩽0.002%
Related substances	+	—
Sodium stearyl maleate	—	⩽0.25%
Stearyl alcohol	—	⩽0.5%
Saponification value (anhydrous basis)	—	142.2–146.0
Organic volatile impurities	—	+
Assay (anhydrous basis)	99.0–101.5%	99.0–101.5%

10 Typical Properties

Acidity/alkalinity: pH = 8.3 for a 5% w/v aqueous solution at 90 °C.
Density: 1.107 g/cm^3.
Density (bulk): 0.2–0.35 g/cm^3
Density (tapped): 0.3–0.5 g/cm^3
Melting point: 224–245 °C (with decomposition)
Solubility: *see* Table II.

Table II: Solubility of sodium stearyl fumarate.

Solvent	Solubility at 20 °C unless otherwise stated
Acetone	Practically insoluble
Chloroform	Practically insoluble
Ethanol	Practically insoluble
Methanol	Slightly soluble
Water	1 in 20 000 at 25 °C 1 in 10 at 80 °C 1 in 5 at 90 °C

Specific surface area: 1.2–2.0 m^2/g.

11 Stability and Storage Conditions

At ambient temperature, sodium stearyl fumarate is stable for up to 3 years when stored in amber glass bottles with polyethylene screw caps.

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

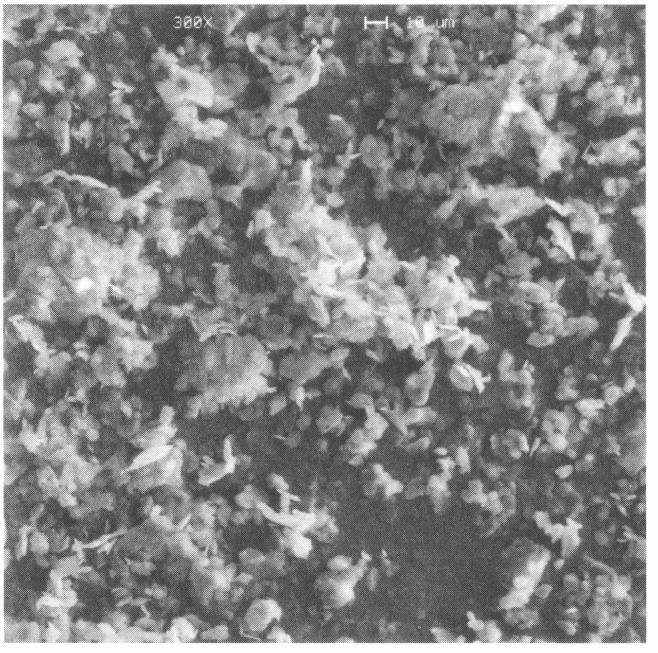
12 Incompatibilities

Sodium stearyl fumarate is reported to be incompatible with chlorhexidine acetate.[10]

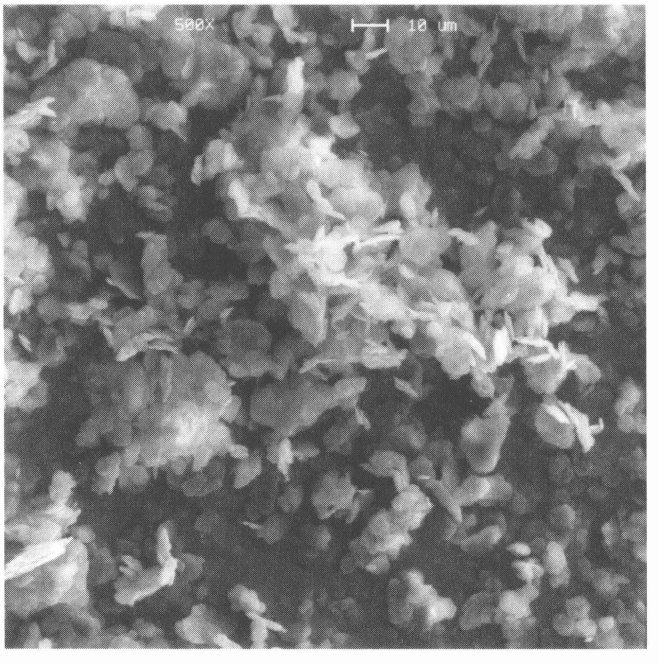
13 Method of Manufacture

Stearyl alcohol is reacted with maleic anhydride. The product of this reaction then undergoes an isomerization step followed by salt formation to produce sodium stearyl fumarate.

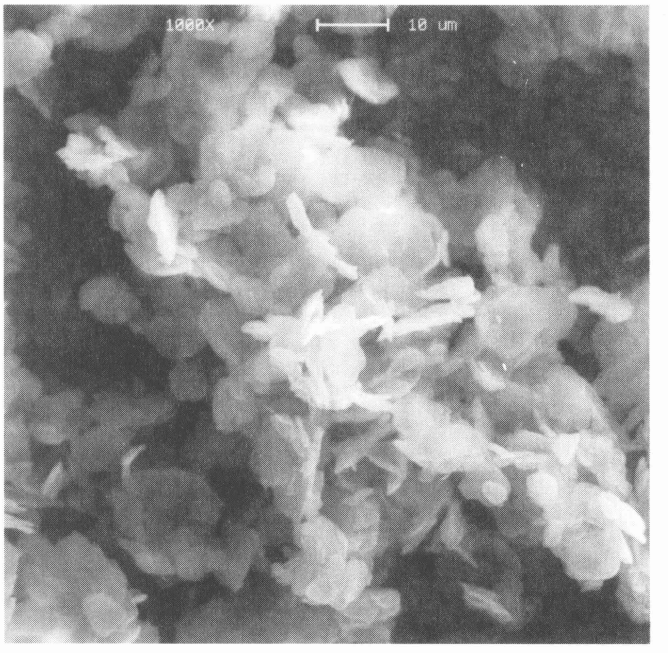
SEM: 1
Excipient: Sodium stearyl fumarate
Manufacturer: Penwest Pharmaceuticals
Lot No.: 255-01
Magnification: 300 ×



SEM: 2
Excipient: Sodium stearyl fumarate
Manufacturer: Penwest Pharmaceuticals
Lot No.: 255-01
Magnification: 500 ×



SEM: 3
Excipient: Sodium stearyl fumarate
Manufacturer: Penwest Pharmaceuticals
Lot No.: 255-01
Magnification: 1000 ×



14 Safety

Sodium stearyl fumarate is used in oral pharmaceutical formulations and is generally regarded as a nontoxic and nonirritant material.

Metabolic studies of sodium stearyl fumarate in the rat and dog indicated that approximately 80% was absorbed and 35% was rapidly metabolized. The fraction absorbed was hydrolyzed to stearyl alcohol and fumaric acid, with the stearyl alcohol further oxidized to stearic acid. In the dog, sodium stearyl fumarate that was not absorbed was excreted unchanged in the feces within 24 hours.[11]

Stearyl alcohol and stearic acid are naturally occurring constituents in various food products, while fumaric acid is a normal constituent of body tissue. Stearates and stearyl citrate have been reviewed by the WHO and an acceptable daily intake for stearyl citrate has been set at up to 50 mg/kg bodyweight.[12] The establishment of an acceptable daily intake for stearates[12] and fumaric acid[13] was thought unnecessary.

Disodium fumarate has been reported to have a toxicity not greatly exceeding that of sodium chloride.[14,15]

See Fumaric Acid, Stearic Acid, and Stearyl Alcohol for further information.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Sodium stearyl fumarate should be handled in a well-ventilated environment; eye protection is recommended.

16 Regulatory Status

GRAS listed. Permitted by the FDA for direct addition to food for human consumption as a conditioning or stabilizing agent

in various bakery products, flour-thickened foods, dehydrated potatoes, and processed cereals up to 0.2–1.0% by weight of the food. Included in nonparenteral medicines licensed in the UK. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets).

17 Related Substances

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18 Comments

Sodium stearyl fumarate is supplied in a pure form and is often of value when the less pure stearate-type lubricants are unsuitable owing to chemical incompatibility. Sodium stearyl fumarate is less hydrophobic than magnesium stearate or stearic acid and has a less retardant effect on tablet dissolution than magnesium stearate.

The EINECS number for sodium stearyl fumarate is 203-743-0.

19 Specific References

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21 Author

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22 Date of Revision

30 May 2002.