

# Zinc Stearate

## 1 Nonproprietary Names

BP: Zinc stearate  
PhEur: Zinci stearas  
USP: Zinc stearate

## 2 Synonyms

*HyQual*; stearic acid zinc salt; zinc distearate.

## 3 Chemical Name and CAS Registry Number

Octadecanoic acid zinc salt [557-05-1]

## 4 Empirical Formula      Molecular Weight

$C_{36}H_{70}O_4Zn$                       632.33 (for pure material)

The USP 25 describes zinc stearate as a compound of zinc with a mixture of solid organic acids obtained from fats, and consists chiefly of variable proportions of zinc stearate and zinc palmitate. It contains the equivalent of 12.5–14.0% of zinc oxide (ZnO).

The PhEur 2002 states that zinc stearate  $[(C_{17}H_{35}COO)_2Zn]$  may contain varying proportions of zinc palmitate  $[(C_{15}H_{31}COO)_2Zn]$  and zinc oleate  $[(C_{17}H_{33}COO)_2Zn]$ . It contains not less than 10.0% and not more than 12.0% of zinc.

## 5 Structural Formula

See Section 4.

## 6 Functional Category

Tablet and capsule lubricant.

## 7 Applications in Pharmaceutical Formulation or Technology

Zinc stearate is primarily used in pharmaceutical formulations as a lubricant in tablet and capsule manufacture at concentrations up to 1.5% w/w. It has also been used as a thickening and opacifying agent in cosmetic and pharmaceutical creams and as a dusting powder. See Table I.

**Table I:** Uses of zinc stearate.

Use	Concentration (%)
Tablet lubricant	0.5–1.5
Water-repellent ointments	2.5

## 8 Description

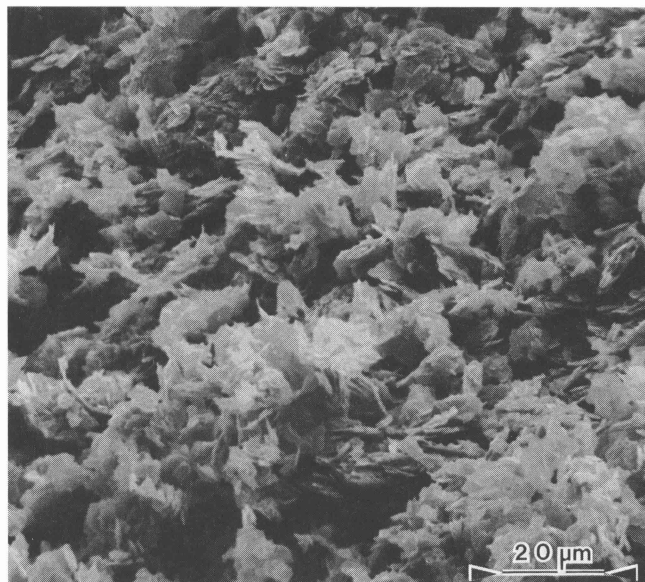
Zinc stearate occurs as a fine, white, bulky, hydrophobic powder, free from grittiness and with a faint characteristic odor.

## 9 Pharmacopeial Specifications

See Table II.

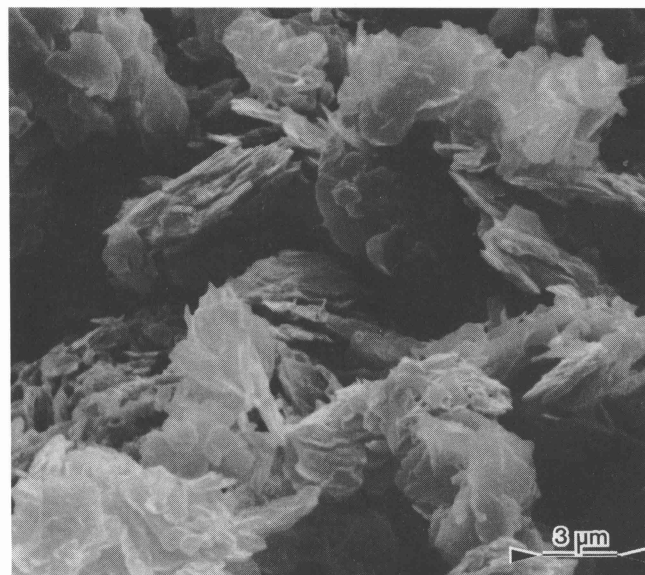
### SEM: 1

*Excipient:* Zinc stearate  
*Magnification:* 600 ×



### SEM: 2

*Excipient:* Zinc stearate  
*Magnification:* 2400 ×



**Table II:** Pharmacopeial specifications for zinc stearate.

Test	PhEur 2002	USP 25
Identification	+	+
Characters	+	—
Acidity or alkalinity	+	—
Alkalis and alkaline earths	—	≤1.0%
Appearance of solution	+	—
Acid value of the fatty acids	195–210	—
Appearance of solution of fatty acids	+	—
Arsenic	—	≤1.5 ppm
Cadmium	≤5 ppm	—
Lead	≤25 ppm	≤0.001%
Chlorides	≤250 ppm	—
Sulfates	≤0.6%	—
Organic volatile impurities	—	+
Assay (as Zn)	10.0–12.0%	—
Assay (as ZnO)	—	12.5–14.0%

### 10 Typical Properties

Autoignition temperature: 421°C

Density: 1.09 g/cm<sup>3</sup>

Density (tapped): 0.26 g/cm<sup>3</sup> for standard grade (Durham Chemicals).

Flash point: 277°C

Melting point: 120–122°C

Particle size distribution: 100% through a 44.5-μm sieve (#325 mesh).

Solubility: practically insoluble in ethanol (95%), ether, and water; soluble in benzene.

### 11 Stability and Storage Conditions

Zinc stearate is stable and should be stored in a well-closed container in a cool, dry place.

### 12 Incompatibilities

Zinc stearate is decomposed by dilute acids.

### 13 Method of Manufacture

An aqueous solution of zinc sulfate is added to sodium stearate solution to precipitate zinc stearate. The zinc stearate is then washed with water and dried. Zinc stearate may also be prepared from stearic acid and zinc chloride.

### 14 Safety

Zinc stearate is used in oral and topical pharmaceutical formulations and is generally regarded as a nontoxic and nonirritant excipient. However, following inhalation, it has been associated with fatal pneumonitis, particularly in

infants.<sup>(1)</sup> As a result, zinc stearate has now been removed from baby dusting powders.

LD<sub>50</sub> (rat, IP): 0.25 g/kg<sup>(2)</sup>

### 15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Zinc stearate may be harmful on inhalation and should be used in a well-ventilated environment; a respirator is recommended. In the UK, the long-term (8-hour TWA) occupational exposure limit for zinc stearate is 10 mg/m<sup>3</sup> for total inhalable dust and 4 mg/m<sup>3</sup> for respirable dust. The short-term (15-minutes) exposure limit for total inhalable dust is 20 mg/m<sup>3</sup>.<sup>(3)</sup>

When heated to decomposition, zinc stearate emits acrid smoke and fumes of zinc oxide.

### 16 Regulatory Status

GRAS listed. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets). Included in nonparenteral medicines licensed in the UK.

### 17 Related Substances

Calcium stearate; magnesium stearate; stearic acid.

### 18 Comments

The EINECS number for zinc stearate is 209-151-9.

See Magnesium stearate for further information and references.

### 19 Specific References

- 1 Ueda A, Harada K, Ueda T, Nomura S. Experimental study on the pathological changes in lung tissue caused by zinc stearate dust. *Ind Health* 1984; 22: 243–253.
- 2 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 10th edn. New York: Wiley, 2000: 3728.
- 3 Health and Safety Executive. *EH40/2002: Occupational Exposure Limits 2002*. Sudbury: Health and Safety Executive, 2002.

### 20 General References

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### 21 Author

LV Allen.

### 22 Date of Revision

28 May 2002.