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Zinc Stearate

Octadecanoic acid, zinc salt;
Zinc stearate
CAS RN[®]: 557-05-1.

DEFINITION

Zinc Stearate is 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 NLT 12.5% and NMT 14.0% of ZnO.

IDENTIFICATION

• **A. IDENTIFICATION TESTS—GENERAL, Zinc(191).**

Sample solution: Mix 25 g with 200 mL of hot water, add 60 mL of 2 N sulfuric acid, and boil until the fatty acids separate as a transparent layer. Cool the mixture, and remove the solidified layer of fatty acids.

Acceptance criteria: A portion of the water layer meets the requirements.

• **B. CONGEALING TEMPERATURE (651).**

Analysis: Place the separated fatty acids obtained in *Identification* test A in a filter wetted with water, and wash with boiling water until free from sulfate. Collect the fatty acids in a small beaker, allow to cool, pour off the separated water, then melt the acids. Filter into a dry beaker while hot, and dry at 105° for 20 min.

Acceptance criteria: The fatty acids congeal at a temperature not below 54°.

ASSAY

• **PROCEDURE**

Sample solution: Boil 1 g of Zinc Stearate with 50 mL of 0.1 N sulfuric acid for at least 10 min, or until the fatty acids layer is clear, adding more water as necessary to maintain the original volume. Cool, and filter. Wash the filter and the flask thoroughly with water until the last washing is not acid to litmus paper.

Analysis: Add to the combined filtrate and washings 15 mL of ammonia–ammonium chloride buffer TS and 0.2 mL of eriochrome black TS. Heat the solution to about 40°, and titrate with 0.05 M edetate disodium VS until the solution is deep blue in color. Each mL of 0.05 M edetate disodium is equivalent to 4.069 mg of ZnO.

Acceptance criteria: 12.5%–14.0% of ZnO

IMPURITIES

Change to read:

• **▲ ARSENIC (211), Procedures, Procedure 1 ▲** (CN 1-JUN-2023)

Test preparation: Mix 5.0 g with 50 mL of water. Cautiously add 5 mL of sulfuric acid, and boil gently until the fatty acids layer is clear and the volume is reduced to about 25 mL. Filter while hot, cool the filtrate, and dilute with water to 50 mL. Transfer a 20-mL aliquot to the arsine generator flask, and dilute with water to 35 mL.

Acceptance criteria: NMT 1.5 ppm

Change to read:

• **▲ LEAD (251), Procedures, Procedure 1 ▲** (CN 1-JUN-2023)

Standard solution: To 20 mL of 0.2 N nitric acid add 5 µg of lead, 4 mL of *Ammonia–Cyanide Solution*, and 2 drops of *Hydroxylamine Hydrochloride Solution*, and shake with 10.0 mL of *Standard Dithizone Solution* for 30 s. Pass through an acid-washed filter paper into a color-comparison tube.

Test preparation: Ignite 0.50 g in a platinum crucible for 15–20 min in a muffle furnace at 475°–500°. Cool, add 3 drops of nitric acid, evaporate over a low flame to dryness, and ignite again at 475°–500° for 30 min. Dissolve the residue in 1 mL of 8 N nitric acid, add 3 mL of *Ammonium Citrate Solution* and 0.5 mL of *Hydroxylamine Hydrochloride Solution*, and render alkaline to phenol red TS with ammonium

hydroxide. Add 10 mL of *Potassium Cyanide Solution*. Immediately extract the solution with successive 5-mL portions of *Dithizone Extraction Solution*, draining off each extract into another separator, until the last portion of dithizone solution retains its green color. Shake the combined extracts for 30 s with 20 mL of 0.2 N nitric acid, and discard the chloroform layer. Add to the acid solution 4.0 mL of *Ammonia-Cyanide Solution* and 2 drops of *Hydroxylamine Hydrochloride Solution*. Add 10.0 mL of *Standard Dithizone Solution*, and shake the mixture for 30 s. Pass the chloroform layer through an acid-washed filter paper into a color-comparison tube.

Acceptance criteria: The color of the *Test preparation* does not exceed that of the *Standard solution* (NMT 10 ppm).

• **ALKALIES AND ALKALINE EARTHS**

Sample solution: Mix 2.0 g with 50 mL of water, and add 10 mL of hydrochloric acid. Boil until the solution is clear, filter while hot, and wash the separated fatty acids with about 50 mL of hot water. Render the combined filtrate and washings alkaline with 6 N ammonium hydroxide. Add ammonium sulfide TS to precipitate the zinc completely, dilute with water to 200 mL, mix, and filter.

Analysis: To 100 mL of the clear filtrate add 0.5 mL of sulfuric acid, evaporate to dryness, and ignite to constant weight.

Acceptance criteria: The weight of the residue does not exceed 10 mg (1.0%).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ZINC STEARATE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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