## Magnesium stearate (Magnesii stearas) (H<sub>3</sub>C -----[CH<sub>2</sub>]<sub>16</sub>-----CO<sub>2</sub>)<sub>2</sub>Mg

## C<sub>36</sub>H<sub>70</sub>MgO<sub>4</sub>

Chemical name. Magnesium stearate; magnesium octadecanoate; CAS Reg. No. 557-04-0.

**Description**. A white, very fine powder of low bulk density; unctuous and readily adheres to the skin; odour, very faint, of stearic acid.

Solubility. Practically insoluble in water, ethanol (~750 g/l) TS, and ether R; slightly soluble in hot ethanol (~750 g/l) TS.

Category. Tablet and capsule lubricant; glidant; antiadherent.

Storage. Magnesium stearate should be kept in a well-closed container.

## Requirements

**Definition.** Magnesium stearate consists mainly of magnesium stearate  $(C_{17}H_{35}CO_2)_2Mg$  with variable proportions of magnesium palmitate  $(C_{15}H_{31}CO_2)_2Mg$  and magnesium oleate  $(C_{17}H_{33}CO_2)_2Mg$ .

Magnesium stearate contains not less than 3.8% and not more than the equivalent of 5.8% of Mg, calculated with reference to the dried substance.

## Identity tests

A. To 5 g add 50 mL of ether R, 20 mL of nitric acid (~130 g/l) TS, and 20 mL of water. Heat under a reflux condenser until completely dissolved, and allow to cool. Separate the aqueous layer, shake the ether layer with two quantities, each of 4 mL, of water, combine the aqueous solutions, wash with 15 mL of ether R, and dilute to 50 mL with water. (Retain this solution for identity test B and for "Chlorides".) Evaporate the ether layer to dryness and dry the residue at 105 °C. The congealing point of the residue is not lower than 53 °C. (Keep the residue for "Acid value of fatty acids".)

B. To 1 mL of the above aqueous solution, add 1 mL of ammonia (~100 g/l) TS; a white precipitate is formed which dissolves on the addition of 1 mL of ammonium chloride (100 g/l) TS. Add 1 mL of disodium hydrogen phosphate (40 g/l) TS; a white, crystalline precipitate is produced.

**Heavy metals**. Use 1.0 g for the preparation of the test solution as described under <u>2.2.3 Limit test for heavy metals</u>, Procedure 4; determine the heavy metals content according to Method A; not more than 20  $\mu$ g/g.

**Chlorides**. Proceed with 2 mL of the aqueous solution from identity test A as described under <u>2.2.1 Limit test for chlorides</u>; the chloride content is not more than 0.25 mg/g.

Loss on drying. Dry to constant mass at 105 °C; it loses not more than 60 mg/g.

Acidity or alkalinity. Boil 1 g with 20 mL of carbon-dioxide-free water R for 1 minute under constant shaking, cool, and filter. To 10 mL of the filtrate add 2 drops of bromothymol blue/ethanol TS and titrate with either hydrochloric acid (0.1 mol/l) VS or sodium hydroxide (0.1 mol/l) VS; not more than 0.05 mL of either titrant is required to obtain the midpoint of the indicator (green).

Acid value of fatty acids. Use 0.2 g of the residue obtained in identity test A and dissolve in 25 mL of the prescribed mixture of solvents; 195-210.

**Assay**. With caution, heat gently about 0.5 g, previously dried and accurately weighed, and gradually ignite until a white residue is obtained. Cool, add 10 mL of hydrochloric acid (~70 g/l) TS, and warm on a water-bath for 10 minutes. Dilute with 25 mL of hot water, add sodium hydroxide (~80 g/l) TS until the solution becomes slightly turbid, and then add 10 mL of ammonium chloride buffer, pH 10.0, TS. Proceed with the titration as described under <u>2.5 Complexometric titrations</u> for magnesium.

Each mL of disodium edetate (0.05 mol/l) VS is equivalent to 1.215 mg of Mg.