

STORAGE

At a temperature not exceeding 30 °C. Do not allow to freeze. If the substance is sterile, store in a sterile, airtight, tamper-proof container.

LABELLING

The label states the declared content of aluminium.

01/2008:1388
corrected 6.0

ALUMINIUM MAGNESIUM SILICATE

Aluminii magnesi silicas

DEFINITION

Mixture of particles with colloidal particle size of montmorillonite and saponite, free from grit and non-swelling ore.

Content:

- *aluminium* (Al; A_r 26.98): 95.0 per cent to 105.0 per cent of the value stated on the label;
- *magnesium* (Mg; A_r 24.30): 95.0 per cent to 105.0 per cent of the value stated on the label.

CHARACTERS

Appearance: almost white powder, granules or plates.

Solubility: practically insoluble in water and in organic solvents.

It swells in water to produce a colloidal dispersion.

IDENTIFICATION

- A. Fuse 1 g with 2 g of *anhydrous sodium carbonate R*. Warm the residue with *water R* and filter. Acidify the filtrate with *hydrochloric acid R* and evaporate to dryness on a water-bath. 0.25 g of the residue gives the reaction of silicates (2.3.1).
- B. Dissolve the remainder of the residue obtained in identification test A in a mixture of 5 ml of *dilute hydrochloric acid R* and 10 ml of *water R*. Filter and add *ammonium chloride buffer solution pH 10.0 R*. A white, gelatinous precipitate is formed. Centrifuge and keep the supernatant for identification C. Dissolve the remaining precipitate in *dilute hydrochloric acid R*. The solution gives the reaction of aluminium (2.3.1).
- C. The supernatant liquid obtained after centrifugation in identification test B gives the reaction of magnesium (2.3.1).

TESTS

pH (2.2.3): 9.0 to 10.0.

Disperse 5.0 g in 100 ml of *carbon dioxide-free water R*.

Arsenic (2.4.2, *Method A*): maximum 3 ppm.

Transfer 16.6 g to a 250 ml beaker containing 100 ml of *dilute hydrochloric acid R*. Mix, cover with a watch glass and boil gently, with occasional stirring, for 15 min. Allow the insoluble matter to settle and decant the supernatant liquid through a rapid-flow filter paper into a 250 ml volumetric flask, retaining as much sediment as possible in the beaker. To the residue in the beaker add 25 ml of hot *dilute hydrochloric acid R*, stir, heat to boiling, allow the insoluble matter to settle and decant the supernatant liquid through the filter into the volumetric flask. Repeat

the extraction with 4 additional quantities, each of 25 ml, of hot *dilute hydrochloric acid R*, decanting each supernatant liquid through the filter into the volumetric flask. At the last extraction, transfer as much of the insoluble matter as possible onto the filter. Allow the combined filtrates to cool to room temperature and dilute to 250.0 ml with *dilute hydrochloric acid R*. Dilute 5.0 ml of this solution to 25.0 ml with *dilute hydrochloric acid R*.

Lead: maximum 15.0 ppm.

Atomic absorption spectrometry (2.2.23, *Method I*).

Test solution. Transfer 10.0 g to a 250 ml beaker containing 100 ml of *dilute hydrochloric acid R*. Mix, cover with a watch glass and boil for 15 min. Allow to cool to room temperature and allow the insoluble matter to settle. Decant the supernatant liquid through a rapid-flow filter paper into a 400 ml beaker. To the insoluble matter in the 250 ml beaker add 25 ml of hot *water R*. Stir, allow the insoluble matter to settle and decant the supernatant liquid through the filter into the 400 ml beaker. Repeat the extraction with 2 additional quantities, each of 25 ml, of *water R*, decanting each time the supernatant liquid through the filter into the 400 ml beaker. Wash the filter with 25 ml of hot *water R*, collecting this filtrate in the 400 ml beaker. Concentrate the combined filtrates to about 20 ml by gently boiling. If a precipitate appears, add about 0.1 ml of *nitric acid R*, heat to boiling and allow to cool to room temperature. Filter the concentrated extracts through a rapid-flow filter paper into a 50 ml volumetric flask. Transfer the remaining contents of the 400 ml beaker through the filter paper and into the flask with *water R*. Dilute this solution to 50.0 ml with *water R*.

Reference solutions. Prepare the reference solutions using *lead standard solution (10 ppm Pb) R*, diluted as necessary with *water R*.

Source: lead hollow-cathode lamp.

Wavelength: 217 nm.

Atomisation device: oxidising air-acetylene flame.

Loss on drying (2.2.32): maximum 8.0 per cent, determined on 1.000 g by drying in an oven at 105 °C.

Microbial contamination. Total viable aerobic count (2.6.12) not more than 10^3 micro-organisms per gram, determined by plate count. It complies with the test for *Escherichia coli* (2.6.13).

ASSAY

Aluminium. Atomic absorption spectrometry (2.2.23, *Method I*).

Test solution. In a platinum crucible mix 0.200 g with 1.0 g of *lithium metaborate R*. Heat slowly at first and ignite at 1000–1200 °C for 15 min. Allow to cool, then place the crucible in a 100 ml beaker containing 25 ml of *dilute nitric acid R* and add an additional 50 ml of *dilute nitric acid R*, filling and submerging the crucible. Place a polytetrafluoroethylene-coated magnetic stirring bar in the crucible and stir gently with a magnetic stirrer until dissolution is complete. Pour the contents into a 250 ml beaker and remove the crucible. Warm the solution and transfer through a rapid-flow filter paper into a 250 ml volumetric flask, wash the filter and beaker with *water R* and dilute to 250.0 ml with *water R* (solution A). To 20.0 ml of solution A add 20 ml of a 10 g/l solution of *sodium chloride R* and dilute to 100.0 ml with *water R*.

Reference solutions. Dissolve, with gentle heating, 1.000 g of *aluminium R* in a mixture of 10 ml of *hydrochloric acid R* and 10 ml of *water R*. Allow to cool, then dilute to 1000.0 ml with *water R* (1 mg of aluminium per millilitre). Into 3

identical volumetric flasks, each containing 0.20 g of *sodium chloride R*, introduce 2.0 ml, 5.0 ml and 10.0 ml of this solution respectively, and dilute to 100.0 ml with *water R*.

Source: aluminium hollow-cathode lamp.

Wavelength: 309 nm.

Atomisation device: oxidising acetylene-nitrous oxide flame.

Magnesium. Atomic absorption spectrometry (2.2.23, *Method I*).

Test solution. Dilute 25.0 ml of solution A, prepared in the assay for aluminium, to 50.0 ml with *water R*. To 5.0 ml of this solution add 20.0 ml of *lanthanum nitrate solution R* and dilute to 100.0 ml with *water R*.

Reference solutions. Place 1.000 g of *magnesium R* in a 250 ml beaker containing 20 ml of *water R* and carefully add 20 ml of *hydrochloric acid R*, warming if necessary to dissolve. Transfer the solution to a volumetric flask and dilute to 1000.0 ml with *water R* (1 mg of magnesium per millilitre). Dilute 5.0 ml of this solution to 250.0 ml with *water R*. Into 4 identical volumetric flasks, introduce 5.0 ml, 10.0 ml, 15.0 ml and 20.0 ml of the solution respectively. To each flask add 20.0 ml of *lanthanum nitrate solution R* and dilute to 100.0 ml with *water R*.

Source: magnesium hollow-cathode lamp.

Wavelength: 285 nm.

Atomisation device: reducing air-acetylene flame.

LABELLING

The label states the content of aluminium and magnesium.

01/2008:0311
corrected 6.0

ALUMINIUM OXIDE, HYDRATED

Aluminii oxidum hydricum

DEFINITION

Content: 47.0 per cent to 60.0 per cent of Al_2O_3 (M_r 102.0).

CHARACTERS

Appearance: white or almost white, amorphous powder.

Solubility: practically insoluble in water. It dissolves in dilute mineral acids and in solutions of alkali hydroxides.

IDENTIFICATION

Solution S (see Tests) gives the reaction of aluminium (2.3.1).

TESTS

Solution S. Dissolve 2.5 g in 15 ml of *hydrochloric acid R*, heating on a water-bath. Dilute to 100 ml with *distilled water R*.

Appearance of solution. Solution S is not more opalescent than reference suspension II (2.2.1) and not more intensely coloured than reference solution GY₆ (2.2.2, *Method II*).

Alkaline impurities. Shake 1.0 g with 20 ml of *carbon dioxide-free water R* for 1 min and filter. To 10 ml of the filtrate add 0.1 ml of *phenolphthalein solution R*. Any pink colour disappears on the addition of 0.3 ml of *0.1 M hydrochloric acid*.

Neutralising capacity. Carry out the test at 37 °C. Disperse 0.5 g in 100 ml of *water R*, heat, add 100.0 ml of *0.1 M hydrochloric acid*, previously heated, and stir continuously; the pH (2.2.3) of the solution after 10 min, 15 min and 20 min is not less than 1.8, 2.3 and 3.0 respectively and is at no time greater than 4.5. Add 10.0 ml of *0.5 M hydrochloric*

acid, previously heated, stir continuously for 1 h and titrate with *0.1 M sodium hydroxide* to pH 3.5; not more than 35.0 ml of *0.1 M sodium hydroxide* is required.

Chlorides (2.4.4): maximum 1 per cent.

Dissolve 0.1 g with heating in 10 ml of *dilute nitric acid R* and dilute to 100 ml with *water R*. Dilute 5 ml of the solution to 15 ml with *water R*.

Sulphates (2.4.13): maximum 1 per cent.

Dilute 4 ml of solution S to 100 ml with *distilled water R*.

Arsenic (2.4.2, Method A): maximum 4 ppm, determined on 10 ml of solution S.

Heavy metals (2.4.8): maximum 60 ppm.

Neutralise 20 ml of solution S with *concentrated ammonia R*, using *metanil yellow solution R* as an external indicator. Filter, if necessary, and dilute to 30 ml with *water R*. 12 ml of the solution complies with test A. Prepare the reference solution using 10 ml of *lead standard solution (1 ppm Pb) R*.

Microbial contamination. Total viable aerobic count (2.6.12) not more than 10^3 micro-organisms per gram, determined by plate count. It complies with the tests for enterobacteria and certain other gram-negative bacteria and with the test for *Escherichia coli* (2.6.13).

ASSAY

Dissolve 0.800 g in 10 ml of *hydrochloric acid R1*, heating on a water-bath. Cool and dilute to 50.0 ml with *water R*. To 10.0 ml of the solution, add *dilute ammonia R1* until a precipitate begins to appear. Add the smallest quantity of *dilute hydrochloric acid R* needed to dissolve the precipitate and dilute to 20 ml with *water R*. Carry out the complexometric titration of aluminium (2.5.11).

1 ml of *0.1 M sodium edetate* is equivalent to 5.098 mg of Al_2O_3 .

STORAGE

In an airtight container, at a temperature not exceeding 30 °C.

01/2008:2166
corrected 6.0

ALUMINIUM PHOSPHATE GEL

Aluminii phosphatis liquamen

DEFINITION

Hydrated AlPO_4 in gel form.

Content: 19.0 per cent to 21.0 per cent of AlPO_4 .

CHARACTERS

Appearance: gel.

Solubility: practically insoluble in water, in ethanol (96 per cent) and in methylene chloride. It dissolves in dilute solutions of mineral acids.

IDENTIFICATION

- Solution S (see Tests) gives reaction (b) of phosphates (2.3.1).
- Solution S gives the reaction of aluminium (2.3.1).
- It complies with the assay.

TESTS

Solution S. Dissolve 2.00 g in *dilute hydrochloric acid R* and dilute to 100 ml with the same acid.