Benzalkonium chloride (Benzalkonii chloridum)

Chemical name. Alkylbenzyldimethylammonium chloride; alkylidimethyl(phenylmethyl)ammonium chloride; CAS Reg. No. 8001-54-5.

Description. A white or yellowish white powder, thick gel, or gelatinous pieces; odourless or a slight aromatic odour.

Solubility. Very soluble in water and ethanol (~750 g/l) TS; freely soluble in acetone R; practically insoluble in ether R.

Category. Antimicrobial preservative; surfactant.

Storage. Benzalkonium chloride should be kept in a tightly closed container, protected from light.

Additional information. Benzalkonium chloride is hygroscopic.

Requirements

Definition. Benzalkonium chloride is a mixture of alkylbenzyldimethylammonium chlorides, the alkyl groups having chain lengths of C₈ to C₁₈.

Benzalkonium chloride contains not less than 95.0% and not more than the equivalent of 104.0% of alkylbenzyldimethylammonium chlorides, calculated as C₂₂H₄₀ClN (relative molecular mass 354.0) and with reference to the anhydrous substance.

Identity tests

A. Shake a solution of 0.1 g in 100 mL of water; it foams strongly.

B. To 5 mL of sodium hydroxide (~80 g/l) TS add 0.1 mL of bromophenol blue TS and 5 mL of chloroform R and shake; the chloroform layer is colourless. Dissolve 10 mg in 1 mL of carbon-dioxide-free water R, add 0.1 mL to the solution above, and shake; the chloroform layer becomes blue.

C. A solution of 10 mg/mL in a mixture of equal volumes of water and ethanol (~750 g/l) TS yields reaction A described under 2.1 General identification tests as characteristic of chlorides.

Sulfated ash. Not more than 20 mg/g.

Water. Determine as described under 2.8 Determination of water by the Karl Fischer method, Method A, using 0.1 g; the water content is not more than 150 mg/g.

Ammonium compounds. Dissolve 0.1 g in 5 mL of water, add 3 mL of sodium hydroxide (1 mol/l) VS, and heat to boiling. Place a moistened strip of red litmus paper R over the solution; no blue colour appears on the paper.

Assay. Dissolve about 2 g, accurately weighed, in sufficient water to produce 100 mL. Transfer 25 mL to a separating funnel, add 25 mL of chloroform R, 10 mL of sodium hydroxide (0.1 mol/l) VS, and 10 mL of a freshly prepared solution of 50 mg of potassium iodide per mL. Shake well, allow to separate, and discard the chloroform layer. Shake the aqueous layer with three quantities, each of 10 mL, of chloroform R and discard the chloroform layers. To the aqueous layer add 40 mL of hydrochloric acid (~420 g/l) TS, allow to cool, and titrate with potassium iodate (0.05 mol/l) VS until the deep brown colour is discharged. Add 2 mL of chloroform R and continue the titration, shaking vigorously, until the chloroform layer no longer changes colour. Carry out a blank titration on a mixture of 10 mL of the freshly prepared potassium iodide solution as described above, 20 mL of water, and 40 mL of hydrochloric acid (~420 g/l) TS and make any necessary corrections.

Each mL of potassium iodate (0.05 mol/l) VS is equivalent to 35.40 mg of C₂₂H₄₀ClN.