Benzalkonium chloride (Benzalkonii chloridum)

Chemical name. Alkylbenzyldimethylammonium chloride; alkyldimethyl(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 C_8 to C_{18}.

Benzalkonium chloride contains not less than **95.0%** and not more than the equivalent of **104.0%** of alkylbenzyldimethylammonium chlorides, calculated as $C_{22}H_{40}ClN$ (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 R 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 $C_{22}H_{40}ClN$.