

ProductInformation

CHLORHEXIDINE DIGLUCONATE 20% Aqueous Solution Sigma Prod. No. C9394

CAS NUMBER: 18472-51-0

SYNONYMS: Abacil; Arlacide G; Hibitane digluconate^{1,2}

PHYSICAL DESCRIPTION:

Appearance: Clear liquid, colorless to very faint yellow in

color, offered as approximately 20% (w/v)² Molecular formula: C₂₂H₃₀Cl₂N₁₀· 2 C₆H₁₂O₇

Formula weight = 897.8

CI NH NH NH NH NH

2 (C₆H₁₂O₇)

STABILITY / STORAGE AS SUPPLIED:

Supplier's suggested shelf-life is three years at 2-8°C.

SOLUBILITY / SOLUTION STABILITY:

Chlorhexidine digluconate is commercially available as a 20% (w/v) aqueous solution since the substance cannot be isolated as a solid. It is soluble in water to at least 50% (w/v) but high viscosity makes such concentrated solutions inconvenient to use. C9394 should not be added directly to 100% alcohol because precipitation may occur.

"Dilute solutions of chlorhexidine (<1.0% w/v) may be sterilized by autoclaving at 115°C for 30 minutes or at 121-123°C for 15 minutes. Autoclaving of solutions greater than 1.0% can result in the formation of insoluble residues and is therefore unsuitable. If sterile solutions are required at such high concentrations, then filtration through a 0.22 µm membrane filter is recommended. Dilute chlorhexidine solutions may be stored at room temperature, and a shelf-life of at least 1 year can be expected, provided that the packaging is adequate. Prolonged exposure to high temperature or light is to be avoided because this can adversely affect the stability of chlorhexidine solutions. All dilute solutions to be stored should be either heat-treated (sterilized or pasteurized) or chemically preserved (4% isopropanol or 7% ethanol) to eliminate the possibility of microbial contamination. For autoclaved solutions the choice of container material is important, best results being achieved with neutral glass or polypropylene. If soda glass is used with chlorhexidine solutions the resultant pH may be above that which is considered optimal for stability (pH 5-7) because of leaching of alkaline materials from the bottle".

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SOLUBILITY / SOLUTION STABILITY: (continued)

"Aqueous solutions of chlorhexidine are most stable within the pH range of 5-8. Above pH 8.0 chlorhexidine base is precipitated and in more acid conditions there is gradual deterioration of activity because the compound is less stable. Hydrolysis yields p-chloroaniline; the amount is insignificant at room temperature, but is increased by heating above 100°C, especially at alkaline pH".³

GENERAL USAGE:

Chlorhexidine digluconate solution has been used as a topical antiseptic and disinfectant effective against a wide range of bacteria, some fungi and some viruses. MERCK INDEX cites a number of articles relating to control of gingivitis, etc. It has been used as an antibacterial agent in commercial ophthalmic products as a replacement for thimerosal (which is a mercury-containing bacteriostat). However, due to skin sensitivity, it has been replaced in ophthalmic preparations by methyl p-hydroxybenzoate ("methyl paraben") or other paraben esters. Its use as a dental disinfectant has led to discoloration of teeth and gums.

A solution of 0.5% in water has been used for general disinfection, particularly in conjunction with cetyltrimethylammonium bromide ("CTAB").⁴

For extensive detailed usage information, please see references 3 and 4.

REFERENCES:

- 1. Merck Index, 12th Ed., #2140 (1996).
- 2. Sigma quality control; Sigma Material Safety Data Sheet.
- 3. Block, S.S., *Disinfection, Sterilization and Preservation*, 4th Ed., (Lea and Febiger, PA, 1991), Ch. 16, p. 274.
- 4. *Martindale: The Extra Pharmacopoeia*, 30th Ed., Ed. Reynolds, J.E.F. (Pharmaceutical Press, 1993), pp. 789-790.

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