

POLYHEXAMETHYLENE BIGUANIDE FOR USE AS AN ANTIMICROBIAL AGENT

Biguanides are an important class of cationic surface-active antimicrobial agents, which have been used for the preservation of many aqueous formulations, in addition to use as disinfectants and antiseptics. The most recognized biguanide used as an antimicrobial is CHG (Chlorhexidine Di Gluconate). Clinical acceptance of CHG has led to the development of new and improved polymeric biguanides, PHMB (Polyhexamethylene Biguanide), for medical use.

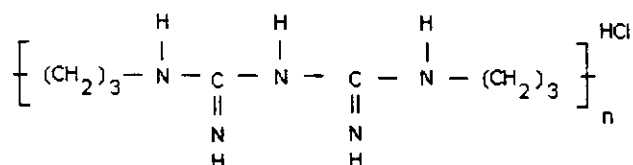


Figure 1. Structural Formula for Polyhexamethylene Biguanide (n=10 to13).

PHMB is available under the trademark Cosmocil® CQ¹. Cosmocil® CQ is listed in the Cosmetic, Toiletry and Fragrance Association (CTFA) Ingredient Directory as polyaminopropyl biguanide. Current applications in the United States include use in cosmetics, contact lens solutions, baby wipes and pool sanitizers². A new use for PHMB is in the medical textile arena. While those products previously listed use preservative concentrations, increased concentrations of PHMB have the ability to suppress microbial growth directly on the fiber when microbial contamination is present. The mechanism of action and lethal event within the microorganism is instability and extensive disruption of the cytoplasmic membrane, which results in leakage of macromolecular components, for example nucleotides³. This is an irreversible action for which the microorganism can not adapt or become “resistant” unlike current concerns with use of antibiotics. Currently there are no known documented cases of resistance to PHMB.

Toxicity of PHMB has been studied extensively in mammalian systems to support its use in medical products⁴. Despite CHG’s lengthy use history, it is well documented that CHG as well as its byproducts during breakdown are cytotoxic. In summary, PHMB has low acute systemic toxicity via the oral and dermal routes. PHMB is poorly absorbed through human skin but when bioavailable the material is rapidly and completely excreted in urine.

FDA has reviewed the antiseptic use of PHMB as an antimicrobial component in wound dressings, and cleared its use in such devices under the pre-market notification (510K) process.

REFERENCES:

1. Cosmocil® CQ is a trademark of Avecia Biocides, Inc.
2. Cosmocil® CQ Antimicrobial Agent- Technical Product Bulletin.
3. Polyhexamethylene Biguanide (PHMB) – A Review of the Mechanism of Antimicrobial Action. 7-94.
4. Cosmocil® CQ- An Antimicrobial Agent for Use in Cosmetics and Pharmaceuticals. 4-94.