



## 6.0 Active ingredient vs. inactive ingredient (preservatives)

3M considers the definition of an active ingredient to be any entity that is necessary to substantiate claims of effectiveness, or is at concentrations greater than would be expected of a preservative. The current TFM does not instruct manufacturers of the percentage limits for preservatives and prohibit claims based on the preservative's activity. Throughout the industry manufacturers list preservatives as inactives, but claim that these preservatives promote effectiveness.

When products must rely upon known active antimicrobials listed as inactive preservatives to pass the proposed test methods it would be appropriate to have them considered as Combination products as well (Table; Topical Antimicrobial Ingredients, Summary of Health-Care Antiseptic Active Ingredients, Pages FR 31435 & 31436).

Specific comments on Alcohol (4<sup>th</sup> Paragraph, FR page 31412) states:

Based on these data the conclusions of the Miscellaneous External Panel (47 FR 22324), the agency concludes that alcohol, when properly formulated, is effective for use as a surgical scrub and antiseptic handwash or health-care personnel handwash. Because it is well documented that alcohol alone does not provide persistence, the agency notes that a preservative agent in the vehicle provided the persistent effect to maintain reduction ....

We believe that the wording of the above paragraph has led to confusion regarding the place of preservatives in the monograph. Numerous manufacturers have interpreted this to mean that as long as only alcohol is declared as the active ingredient any level or number of antimicrobials may be added to increase efficacy. This has even progressed to the point of making efficacy claims based on the inclusion of preservatives, yet labeling the added materials as inactive compounds,

The requirements for antimicrobials used as preservative ingredients differ substantially from those applicable to antimicrobials used as drugs. The agency appears to have dropped the wording, clarifying the use of preservatives, it had previously used. In the January 1978 tentative order the agency proposed the following definition of antimicrobial preservative:

*"Antimicrobial preservative (inactive) ingredient. A compound or substance that kills microorganisms or prevents or inhibits their growth and reproduction and is included in a product at a concentration sufficient to prevent spoilage or prevent growth of inadvertently added microorganisms, but does not contribute to the claimed effects of the product in which it is included,"* (Food and Drug Administration (1978a) *Over-the-counter drugs generally recognized as safe, effective and not misbranded*. OTC Topical Antimicrobial Products. Fed. Reg. 43:1210-1249. January 6, 1978).

The referenced wording should be reinserted in order to help all parties, manufacturers and consumers, understand the role of preservatives. Acceptable preservative concentrations (%) of common antimicrobials should be stated.