

054901

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 02/04/86 *WEC* OUT 04/29/86
William E Campbell
Reviewed by William Campbell, Jr. Date 04/29/86

EPA Reg. No. or File Symbol 42182-1EPA Petition or EUP No. NONEDate Division Received 12/13/85Type Product(s): I, (D,) H, F, N, R, SData Accession No(s) NONEProduct Mgr. No. 32 (Kempter)Product Name(s) Microban Plastaic Additive "B"Company Name (s) Microban ProductsSubmission Purpose Protocol Review/ResubmissionChemical & Formulation Powder

Active Ingredient (s):

8

5-Chloro-2-(2,4 dichlorophenoxy) phenol 99.0

The following comments are in response to the questions raised in the registrants letter of October 10, 1985 concern- a test procedure and labeling claims for residual self sanitizing activity for hand rails molded or extruded from polymers containing Microban Plastic Additive "B". The questions are answered in the order asked.

1. Have other materials (surfaces) been tested and approved by EPA as "self-sanitizing" or are we the first to attempt this designation for a solid surface?

The Agency has not accepted a residual self-sanitizing claims for a hard non-porous surface impregnated with an antimicrobial agent. The highest level a activity accepted for impregnater items has been bacteriostatic activity.

2. If the Microban® surface provides 99.9% kill in five minutes, we assume that this provides the basis for a generic claim for self-sanitizing capability as specified in William Campbell's letter of October 25, paragraph (h.). No continuing time element is required for the basic claim.

Paragraph (h) of the letter of October 25, 1984 states that the results must show a bacterial reduction of at least 99.9% over the parallel control counts within five minutes of each inoculation/reinoculation, for the period of time the product is intended or claimed to be self-sanitizing-in use. To show a 99.9% reduction in 5 minutes after only one (1) inoculation is not adequate to support a self-sanitizing claim for an impregnated article.

3. If (2) is accomplished, then the remainder of the test will determine the length of time for which self-sanitization can be claimed as specified in paragraph (d.) (ibid).

Acceptance of a self-sanitizing claim for the proposed use ~~often~~^{must} must be for a period or time the impregnated item is intended or claimed to be self-sanitizing in use.

4. Upon satisfactory completion of (2), we suggest that the claim be modified as follows until the actual time period is established. "Self-sanitizing for time periods depending upon conditions of use."

The proposed claim would not be acceptable for the reasons indicated above.

To date, the only accepted residual self-sanitizing claims have been for single use items such as hospital linens. Claims for this level of activity have not been accepted for treated articles that are intended to provide this activity after multiple uses and for an extended period of time. Therefore a time period of intended activity has not been required for single use items. The registrant is reminded that the registration for the product can be amended to extend the claimed time period for self-sanitizing activity if a short time period is initially claimed.