

SEP 10 1993

Metrex Research Corporation  
10270 S. Progress Way  
Parker, CO 80134

Attn: Brad E. James

Subject: MetriCide  
EPA Registration No. 46781-1

MetriCide 28  
EPA Registration No. 46781-2

MetriCide Plus 14  
EPA Registration No. 46781-3 ✓

MetriCide Plus 30  
EPA Registration No. 46781-4

Amendments dated April 23, 1993

The amendments referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, to add new "tuberculocidal claims with efficacy data" are not acceptable.

The submitted Quantitative Tuberculocidal Test data to support the new TB claims are not acceptable for the following reasons.

1. Product failed to meet the EPA's performance standard which is 100% kill of a 10<sup>6</sup> colony forming units/ml in suspension.
2. Data were not developed on 14 day reused solution to support 30 day reuse claim.
3. No validation data were submitted as required by EPA's TB Data Call-In Notice for glutaraldehyde products.
4. Data were derived from only three studies instead of required four independent studies.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

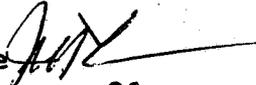
5. Two unauthorized modifications were employed:

- a. Culture was not grown/prepared as specified in the method.
- b. Culture was grown in 7H9 media instead of Modified Proskauer-Beck Medium.

The Agency reserve all labeling review until the data have been corrected in accordance with the above items and resubmitted for our review. Note: All data must be properly formatted in accordance with PR Notice 86-5.

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 305-6982.

Sincerely,

John H. Lee   
Product Manager 31  
Antimicrobial Program Branch  
Registration Division H7505C