

200.0 **Introduction:**

200.1 **Uses(s)**

See attached proposed label.

200.2 **Background Information:**

The submission received 04-27-93, is an amendment to add new tuberculocidal claim (99.92% TB kill claim/5.3 log reduction in counts) with efficacy data and revised label.

201.0 **Data Summary**

201.2 **Brief Description of Test:**

"Quantitative Tuberculocidal Test (Survival Curve and D-Value Calculation)" by Aliene Borgus, MicroBio Test, Inc. (MBT), 14280 Sullyfield Circle, #200, Chantilly, Virginia 22021, dated 12-09-92 (MRID No. 427508-01).

201.2 **Data Summaries**

See 202.0.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol 46781-3

Date Division Received 04-27-93

MRID No (s) 427508-01

Product Manager PM 31 (Lee)

Product Name MetriCide Plus 14

Company Name Metrex Research Corporation

3

202.0 **Recommendations**

202.2 **Efficacy Not Supported by the Data:**

"Quantitative Tuberculocidal Test (Survival Curve and D-Value Calculation)" by Aliene Borgus, MicroBio Test, Inc. (MBT), 14280 Sullyfield Circle, #200, Chantilly, Virginia 22021, dated 12-09-92 (MRID No. 427508-01).

The submitted Quantitative Tuberculocidal Test data are not acceptable because:

1. Product failed to meet the EPA's performance standard which is 100% kill of a 10^6 colony forming units/ml in suspension.
2. Data were not developed on 14 day reused solution to support 14 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.
5. Two unauthorized modifications were employed:
① Culture was not grown/prepared as specified in the method, and culture was grown in 7H9 media
② ~~instead of Modified Proskauer-Beck Medium.~~
6. Data were not developed on Metricide Plus 14.

203.0 **Labeling:**

The proposed amendment is not acceptable because testing performed was not according to the EPA Guidelines requirements and EPA's TB Data Call-In Notice.

4