Technical Support Section Efficacy Review-II

Disinfectants Branch

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Product Manager No. PM 31 (Lee)

Product Name Metricide Activated Dialdehyde Solution

Company Name Metrex Research Corporation

202.0 Recommendations

202.1 Efficacy Supported By Data

The submitted re-use data support efficacy of an undiluted activated solution when reused for 14 days for sterilization in 10 hours at 20°C and/or disinfection in 10 minutes at 20°C in accordance with label directions.

These data will also support efficacy claims for the 14-day reused solution against the following microorganisms:

Pseudomonas aeruginosa	Herpes simplex virus, Type 1
Staphylococcus aureus	Herpes simplex virus, Type 2
Salmonella choleraesuis	Poliovirus, Type 2
Trichophyton mentagrophytes	Adenovirus, Type 2
Bacillus sublitis	Echovirus., Type 8
Clostridium sporogenes	

202.2 Efficacy Not Supported By Data

The efficacy claim against Coxsackievirus, B5a, is not acceptable because the data indicate that the 14-day reused solution does not completely inactivate this virus.

202.3 Tuberculocidal Efficacy

The submitted data developed by the AOAC Tuberculocidal Activity Test appear to demonstrate effectiveness of a 14-day reused solution as a tuberculocide in 10 minutes at 20°C. However, since the Agency has evidence that reused solutions of glutaraldehyde-based products may not provide consistently effective tuberculocidal results in 10 minutes at 20°C, validation testing is recommended in order to accept tuberculocidal data derived for 10-minute/20°C use conditions.

202.4 Validation Testing

As indicated in the Pesticide Assessment Guidelines, Subdivision G, the Agency reserves the option to perform its own test for validation of efficacy of products selected on a case-by-case basis. However, due to curtailment of laboratory operations at the EPA microbiology laboratory at Beltsville MD, the Agency must rely upon validation data derived by other independent laboratories commissioned by the registrant.

The validation testing should be conducted on a 14-day reused solution by the same tuberculocidal test employed in developing the submitted data. Thus the solution to be tested should be stressed for 14 days in accordance with EPA-approved simulated-reuse procedures; then an aliquot of the stressed solution should be sent to 2 different laboratories for assay at 10 minutes and 20°C in accordance with procedures specified in the AOAC Tuberculocidal Activity Test.

202.3 Labeling

The efficacy claim against Coxsackievirus B5a is not support by acceptable data and must be deleted.

The label review can not be completed until the tuberculocidal validation data are submitted.