

01 OCT 1982

Metrex Research Corporation  
P.O. Box 272  
Littleton, CO. 80160

Attn: Mr. David L. Stump

Subject: Activated Dialdehyde (Powder Activator)  
EPA File Symbol 46781-R

We have determined that subject product is sufficiently similar to the referenced product, EPA Reg. No. 7078-1, and that other data in our files may be used to support registration. However, you must submit confirmatory data to demonstrate biological equivalency.

The confirmatory data are generally required in other situations where biological equivalency must be established based on AOAC standard test.

Confirmatory Data:

1. Disinfectant Claims: Employ the AOAC use-Dilution test on one batch (60 day old and 14 days activated) ten (10) carriers for each of three organisms (S. aureus, S. choleraesuis, P. aeruginosa). Additionally, no confirmation of virucidal/tuberculocidal data are required.

2. Sterilizing claims: Employ the AOAC Sporocidal test on one batch (60 day old and 14 days activated) 30 cylinders and 30 suture loops each against each of the following organisms: B. subtilis and C. sporogenes. Sporocidal activity must be confirmed, in our Beltsville laboratory, within six (6) months after registration.

It must be understood that the offer to pay compensation under 40 CFR 162.9-4 and -5 includes efficacy data in support of registration for subject product. Additionally, submit the required Certification Statement, revised 8/16/79.

We reserve label comments until the above requested data package has been submitted and reviewed. Finished printed labeling must not be submitted at this time.

Sincerely,

John H. Lee  
Product Manager 31  
Disinfectants Branch  
Registration Division (TS-767C)