UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

2 MAY 1980

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Reevaluation of 90-day studies (rat and dog) on Dowicil. Cas #181.

TO: Dr. Kenneth Bailey
Toxicology Branch
Hazard Evaluation Division

Looking at the total information and reviews we have on Dowicil the following becomes apparent:

1. FDA has reviewed two 90-day rat studies with consecutive dose ranges (1,2,4, 7.5, 15, and 30 mg/kg/day). Their conclusion is that 2 mg/kg/day is a NOEL for this chemical. FDA also has reviewed the 90-day dog study (7.5, 15 and 30 mg/kg/day doses) and has concluded that a NOEL has not been established. See attached review of May 24, 1979, by Dr. Kayajanian approved by Dr. Misra.

2. EPA on the otherhand, has determined that the 7.5 mg/kg/day in the dog is a NOEL but that on the otherhand, a new "rat study" is needed, presumably because the previous study or studies are inadequate.

Before going any further on this compound it seems necessary to resolve this discrepancy one way or another. By this memo we are requesting a resolution by classifying the studies in question according to the core concept, that is are they useful in making a regulatory decision. - Since this matter has been hanging around for some time now, your speedy review is appreciated.

The "residue question" is being addressed by Chemistry Branch. Receiving the Tox and RCB input will allow us to proceed further with the registrant.

Reto Engler, Chief
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