

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: APR 23 1980

SUBJECT: Clearance of Dowacil 75 as a Preservative Under 40 CFR 180.1001 (d).
Caswell #181FROM: Kenneth L. Bailey
Toxicology Branch/HED (TS-769)*Ken Bailey*TO: A. E. Castillo, PM #34
Registration Division (TS-767)THRU: William L. Burnam, Acting Chief
Toxicology Branch/HED (TS-769)*W. L. Burnam for W. L. Durman
4/23/80*

NOTE: It is to be noted that Dowacil 75 is a mixture of two separate and distinct chemical compounds, the cis and the trans isomers of 1-(3-chlorallyl)-3,5,7-triaza-1-azoniaadamantan chloride. Thus, any testing to support the use of Dowacil-75 must be conducted using both the cis isomer and the trans isomer and not just the cis isomer as was the case with the recently submitted Ames Study.

I. History:

At different times, but apparently for the same reason, both R. Engler and K. Bailey have rejected this request. At least one reason for concern about this compound relates to the fact that it contains a vinyl chloride moiety within its structure. While this vinyl chloride moiety raises questions about Dowacil, this does not mean that there is any convincing reason to believe that the two compounds, Dowacil and vinyl chloride, will behave similarly in man.

In order to resolve this question concerning Dowacil 75 a meeting was held. This meeting was attended by R. Engler, RD and K. Bailey, HED and a Dow representative. In this meeting it was decided that the best way to resolve the question concerning Dowacil 75 was to use an Ames Study for screening purposes. The basic idea was that, should Dowacil yield negative results in an Ames Study, no additional studies would be required at this time. Further, it was understood that all deficient studies on hand would be corrected.

II. Review:

See attached G. Burin review for details; see also the attached 3-10-78 memo to A. E. Castillo.

III. Recommendation:

In order to adequately evaluate this compound we require that the following studies be conducted using Dowacil 75:

- o An adequate Ames study.
- o An acceptable rat 90-day feeding study-see attached reviews for details.

If the product is cleared, it should be cleared under 40 CFR 180.1001 (d) with a preemergence restriction.

Attachment:

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