UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: January 19, 1978

SUBJECT: Clearance of an Inert Ingredient

FROM: D. Ritter, Adjuvants Toxicologist
Tox/Rd WH-567

TO: J. M. Shaughnessy, RET Leader
PCB/RD WH-567
CHM/RD WH-567

Dowicil 75 Preservative; letter of June 30, 1977, Dow Chemical Co., Midland, Michigan, 48640.

Use: Preservative

Restrictions: 1.0% of Formulation by weight.
Clearance sought: (d).

In our most recent comments on this proposal (11/17/77, D. L. Ritter) we refused clearnace because of toxicity data deficiencies. Data required included ninety day feeding studies in rats and dogs to be submitted.

Company has now provided information that several Food Additive Petitions have been filed with FDA and that requisite studies were reviewed by FDA toxicologists and recommendations made.

We visited FDA (1/18/78) and determined that the following studies were accepted by FDA:

90 day rat feeding NEL = 7.5 mg/kg/day (150 ppm) 1/
(systemic effects).

90 day dog feeding NEL = 7.5 mg/kg/day (300 ppm) 2/
(systemic effects).

We examined these reviews closely and concluded that the studies are CORE Guideline, for purpose of re-registration.

Accordingly, our previous objections to this clearance are answered.

Recommendation:

Amend 40 CFR 180.1001 (d) by adding 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride.
Restriction: to 1% of formulation
Use: Preservative.

EPA FORM 1320-6 (REV. 3-76)

Bases for the recommendation:

1. Ninety rat dog and rat ffeeding studies available
2. Restriction as to amount (1%) in formulations.

1/ Review of FAP#4B2900, J. L. Couvillion, Ph.D., February 2, 1974.

2/ Review of FAP#6B3224, D. S. Shawney, Ph.D., November 9, 1976.