

SHAUGHNESSEY NO.

059001

EEB BRANCH REVIEW

DATE: IN 8/6/82 OUT 8/31/82

FILE OR REG. NO. 241-220

PETITION OR EXP. PERMIT NO. _____

DATE OF SUBMISSION 12/21/81

DATE RECEIVED BY HED 8/6/82

RD REQUESTED COMPLETION DATE 9/7/82

EEB ESTIMATED COMPLETION DATE 8/31/82

RD ACTION CODE/TYPE OF REVIEW 650/

TYPE PRODUCT(S): I, D, E, F, N, R, S Insecticide

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME(S) Abate

American Cyanamic Company

Registrant Response to ReRegistration

COMPANY NAME _____

SUBMISSION PURPOSE Package - Data Waiver Request

SHAUGHNESSEY NO. CHEMICAL, & FORMULATION Z A.I.

100

Purpose of Submission

American Cyanamid requests a waiver of the following studies required per the Temephos Registration Standard (1981).

1. Avian single dose oral LD₅₀ for technical.
2. Fish acute LC₅₀ for granulars.
3. Acute toxicity to aquatic invertebrates for emulsifiable concentrates.
4. Acute toxicity to estuarine and marine organisms for technical, emulsifiable concentrate and granular.
5. Seed germination/emergence and vegetative vigor for technical.

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Discussion

Respective comments to the above are as follows:

1. The registrant submitted a study* in support of the avian single dose oral LD₅₀ requirement. The study is not acceptable to fulfill this requirement for at least two reasons; one, it is a seven day feeding study, more appropriate to a subacute dietary study than an acute oral study. Secondly, the test species, Japanese quail, is not a recommended specie at this time. Incomplete data show temephos to be highly toxic to birds (LD₅₀=30-80 mg/kg).

A definitive LD₅₀ of the technical by oral intubation to a waterfowl (preferred since most, if not all, uses are direct application to water) is needed: to determine precautionary labeling; to compare with measured or estimated residues in the environment (for granular formulations the number of granules necessary to be consumed to reach the LD₅₀); to determine if additional data are necessary in the laboratory or field; for comparison with toxicity levels of other organisms and other pesticides; and, ultimately, as part of the data base, to indicate whether populations of birds exposed to temephos are likely to be significantly reduced by acute poisoning.

- 2/3. No data were submitted that would satisfy requirements for 2 and 3 above. Laboratory data on the appropriate LC₅₀ for fish and aquatic invertebrates of end-use formulated products added directly to water are needed: to determine precautionary labeling indicating, among other items, the toxicity and potential hazards of end-use formulations [The inert ingredients in a formulation may enhance the toxicity of the active ingredient or have some inherent toxicity to fish themselves. We have data to indicate that an EC and a granular (Riverdale 5%G) can be ~20X more toxic than the technical. The effect of inert ingredients upon the toxicity and consequently the hazard of a pesticide formulation to fish is of greatest concern when

*Exhibit 14, Seven Day Repeated Feeding Study to Young Coturnix Quail, American Cyanamid Co., May 12, 1965.

the formulated product is introduced directly into the aquatic environment]; to compare with measured or estimated residues of the end-use product in water; to determine if additional data are necessary; for comparison with toxicity levels of other organisms and other pesticides; and, ultimately, as part of the data base, to indicate whether population of these organisms exposed to the formulated product are likely to be significantly reduced by acute poisoning.

4. American Cyanamid per letter dated 12/21/81, indicated they are desirous of canceling temephos use on food crops (i.e. citrus, Biothion® 6E, 241-233). This eliminates the need for estuarine and marine testing for the technical grade of the active ingredient and effectively reduces testing costs by approximately \$3100. However, temephos products are intended for direct application to the estuarine environment. Additionally, an ingredient in the end-use formulation other than the active ingredient is expected to enhance (as discussed above) the toxicity or to cause toxicity to estuarine organisms. Laboratory studies, then, on the LC50 for mollusc, shrimp and fish are needed for the EC and granular to determine precautionary labeling, to compare with measured or estimate residues in water, to determine if additional data are needed and for risk determinations.
5. EEB concurs with the waiver request of 5 above. At this time the Agency is requiring these data on a case by case basis per 158 of the Proposed Guidelines. We do not feel these data are needed at this time. In case any future phytotoxicity problems arise we may ask for these data.

Based on our best estimate, the total costs for the ecological effects data requested are approximately \$8600.00. It is EEB's opinion that American Cyanamid's estimate of the domestic usage of temephos (based on 65,000 lbs sold and a use rate of 0.03 lb a.i./A) on 2,167,000 surface acres of water or wetlands is further justification for asking for these relatively inexpensive data for a chemical that can be used in areas with commercially valuable aquatic species.

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Conclusions

EEB has considered the request for a waiver of the ecological effects data requirements (100 above) set forth in the Temephos Registration Standard. The following conclusions apply:

1. Data waivers are -
 - a. estuarine studies for technical.
 - b. seed germination/emergence and vegetative vigor.

ATTACHMENT II

2. Data requirements (with guidelines citation no.) are -
 - a. avian acute oral LD₅₀ for technical (71-1).
 - b. fish acute LC₅₀ for 5% G (72-1).
 - c. aquatic invertebrate LC₅₀ for 40-60% EC (72-2).
 - d. acute toxicity to estuarine organisms for EC and G (72-3).

Note: Cyanamid contends they only sell Abate technical (although their technical bulletin indicates that Cyanamid markets liquid and granular formulations of Abate worldwide). If Cyanamid does only sell Abate technical domestically, the decision whether Cyanamid need only submit data pertinent to registration of technical (MUP, and would thus not be responsible for formulated product testing) should be made by RD or someone other than EEB. We are of the understanding, per Herb Harrison, that American Cyanamid, as the basic U.S. producer of temephos, is responsible for all data requirements.

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Per conversation with Rick Stevens dated 12-7-82, the growth and reproduction of aquatic plants (163.122-2) should be incorporated in item #5 of review. Data waiver is granted for this requirement also.

J. Edwards
12-7-82