

Shaughnessy Number: 81901

Date out of EFGWB: NOV 29 1989

To: Dona Williams
Product Manager 74
Registration Division (H7505C)

From: Emil Regelman, Supervisory Chemist
Environmental Fate Review Section #2
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Thru: Hank Jacoby, Acting Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Attached, please find the EFGWB review of...

Reg./File #: 50534-7

Chemical Name: Chlorothalonil

Type Product: fungicide

Product Name: Bravo

Company Name: Fermenta (formerly Diamond Shamrock)

Purpose: clarification of status of fish bioaccumulation data requirement

Date Received: 11/6/89

Action Code: 660

EFGWB#(s): 90-0053

Total Reviewing Time (decimal days): 1.5 days

Deferrals to: Ecological Effects Branch, EFED

Science Integration and Policy Staff, EFED

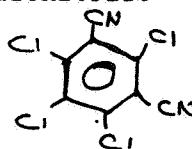
Non-Dietary Exposure Branch, HED

Dietary Exposure Branch, HED

Toxicology Branch

1. CHEMICAL:

chemical name: 2,4,5,6-tetrachloroisophthalonitrile
common name: chlorothalonil
trade name: daconil
structure:



CAS #: 1897-45-6
Shaughnessy #: 081901

2. TEST MATERIAL: n.a.

3. STUDY/ACTION TYPE: discussion of fish bioaccumulation requirement set forth in 1988 draft Registration Standard

4. STUDY IDENTIFICATION: n.a.

5. REVIEWED BY:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

E.B. Conerly 11/23/89

6. APPROVED BY:

Typed Name: Emil Regelman
Title: Supervisory Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

E. Regelman
NOV 29 1989

7. CONCLUSIONS:

The fish accumulation study is not acceptable, and the deficiencies are such that EFGWB does not believe it can be made acceptable by additional data or explanation. A new study is required.

8. RECOMMENDATIONS:

A new fish bioaccumulation study should be initiated as soon as possible, with close attention to avoiding the problems which caused the present study to be rejected.

9. BACKGROUND:

Two parts of the Registration Standard are inconsistent:

In the executive summary portion, the reviewed fish bioaccumulation studies were deemed acceptable, and the results described.

In the detailed review section, they were deemed unacceptable because, instead of "pure" parent compound, the fish were exposed to a mixture of parent and degradates in roughly equal amounts. The reviewer speculated that the compound might have undergone hydrolysis under these conditions.

The applicant contends that this study should be considered acceptable, and explains that the mixture of compounds in the exposure aquarium results from metabolism.

Reexamination of the main study (MRID # 86629) reveals the following:

- 1) The tank contained a nominal 0.008 ppm of pesticide (0.008 mg/l). Flow-through of pesticide-water in the tanks was at the rate of 500 ml/minute (equivalent to 0.004 mg pesticide/minute).
- 2) The concentration of chlorothalonil was very low by day 14 of exposure, 0.0004 ppm vs a nominal 0.008 and an observed 0.0059 ppm total ¹⁴C.
- 3) The nominal concentration employed in the study was well below the solubility limit for the compound which has been independently reported as 0.6 ppm (Farm Chemicals Handbook), and also well below the concentration at which toxic effects had been observed (20% mortality at 0.1ppm).

Reviewer's Comments:

- 1) This study is not acceptable for satisfying data requirements, because the fish were not exposed to a constant concentration of parent, and, in fact, were apparently exposed to a constantly changing undefined mixture of compounds.
- 2) The assessment contained in the detailed report on the study should be considered correct. The executive summary portion of the standard should be revised accordingly.
- 3) It seems much more likely that the observations were due to some technical problem with pesticide addition or mixing in the tank.
- 4) The long period during which retention of residues was observed argues against rapid metabolism and excretion. Only 50% of the residues in the edible portions were depurated in ten days.

Suggestions for the new study:

- 1) When a new study is performed, EFGWB recommends that it be done using the highest concentration consistent with solubility constraints and avoidance of toxic effects to the fish.
- 2) The contents of the aquarium water should be sampled and analyzed frequently, to ensure that the exposure conditions are as intended.

The status of data requirements is as follows:

hydrolysis -- fulfilled, stable at pH 5 and 7, 10% degrades in 30 days at pH 9, with 2,4,5,6-tetrachloroisophthalimide as the sole degradate
photolysis in water -- not fulfilled
soil photodegradation -- not fulfilled
aerobic soil metabolism -- not fulfilled
anaerobic soil metabolism -- fulfilled by submission of acceptable anaerobic aqueous metabolism
leaching/adsorption/desorption -- fulfilled; lab studies indicate low leachability, but findings in ground water have triggered monitoring requirements
terrestrial field dissipation -- partially fulfilled
confined accumulation on rotational crops -- fulfilled, field studies indicate the need for establishment of tolerances
fish bioaccumulation -- discussed in this review

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: n.a.

11. COMPLETION OF ONE-LINER: no information added

12. CBI APPENDIX: n.a.