

US EPA ARCHIVE DOCUMENT

FILE COPY

Date Out EFB: FEB 6 1981

To: Product Manager 21 Jacoby
TS-767

From: Dr. Willa Garner ^{lll}
Chief, Review Section No. 1
Environmental Fate Branch

Attached please find the environmental fate review of:

Reg./File No.: 677-313

Chemical: Chlorothalonil

Type Product: Fungicide

Product Name: Bravo 500

Company Name: Diamond Shamrock

Submission Purpose: conditional registration for use on soybeans, orange, and
grapefruit

ZBB Code: 3(c)(7)

ACTION CODE: 336

Date in: 11/12/81

EFB # 740

Date Completed: FEB 6 1981

TAIS (level II)

Days

Deferrals To:

63

8

Ecological Effects Branch

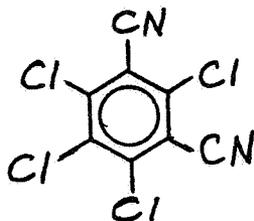
Residue Chemistry Branch

Toxicology Branch

1.0 Introduction

Diamond Shamrock has responded in rebuttal to EFB review and evaluation of data requirements for conditional registration of chlorothalonil on (a) soybeans, and (b) grapefruit and oranges. They continue to seek conditional registration for these uses. EFB has examined and evaluated the applicant's responses to the original EFB evaluation/review. This evaluation is summarized in section 2.0. The complete original Agency letter and applicant response are attached as an appendix for informational purposes.

Chlorothalonil = Bravo 500



Active ingredient = tetrachloroisophthalonitrile = 40.4%

Inert ingredients = 59.6%

Bravo 500 = 4.17 lb chlorothalonil/gallon See EFB reviews of 10/20/80 and 10/21/80 for directions for use.

2.0 EFB response to applicants rebuttals of original EFB review.

A. Soybean use

1. EPA comment: An anaerobic soil metabolism study using soil aged at 25 °C will be required.

Applicant response: A previously submitted study is cited which allegedly satisfies this requirement.

EPA response: This study was reviewed previously by EPA (Ney and Terkowitz-4/27/76) and found to be unacceptable. Therefore, submission of an acceptable anaerobic soil metabolism study remains a condition of registration.

2. EPA comment: A previously submitted field dissipation study was noted as concerned only with the parent compound and lacking in soil profiles.

Applicant response: A previously submitted study ("Evaluation of the Leaching of Chlorothalonil Under Field Conditions...") was cited as satisfying these concerns.

EPA response: According to EC review of 6/3/75 (Ney and Schenk), the above-cited study is valid and shows that chlorothalonil and its major degradate DAC-3701 will not accumulate in soil under field conditions. EFB will therefore concur that the two submitted field studies satisfactorily define the field dissipation of chlorothalonil.

3. EPA comment: A catfish accumulation study is needed.

Applicant response: A study report will be completed by April, 1981.

EPA response: EFB wishes to review the data as soon as possible.

4. EPA comment: Deficiencies in the studies on effects of pesticide on microbes are reiterated.

Applicant response: Studies addressing these deficiencies are under way and will be completed by April, 1981.

EPA response: EFB wishes to review the data as soon as possible.

5. EPA comment: EFB notes the use of soil sieving in the adsorption/desorption study and questions what effect the sieving had on the K values derived.

Applicant response: The sieving, done according to proposed EPA Guidelines, did not alter the adsorption characteristics of the soils and, therefore, had little or no effect on the experimental K values.

EPA response: EFB notes that it is unclear whether the soil characterization provided was done on sieved soil. Sieving will have an effect on adsorption since it effectively increases the % organic matter content of the soil. While 1975 Guidelines permit the use of soil sieving, they also require an accounting of the weight removed by sieving for a later accounting of adsorption on a whole soil basis. Therefore, the K values appear biased to underestimate leaching potential and the original EFB comment/question remains. The answer is especially critical for evaluating the proposed citrus use which involves sandy areas.

6. EPA comment: A need for an 18 month rotational crop restriction is noted based on laboratory data. A field rotational crop study is needed to remove this restriction.

Applicant response: A discussion of chlorothalonil soil degradation products is given, intending to provide a rationale as to why rotational crop data are unnecessary.

EPA response: The applicant has not responded to EFB concerns. A field rotational crop study is required for this proposed major use. EFB notes that changes in rotational policy (i.e. establishing tolerances for residues on rotated crops) may remove the need for the rotational crop restriction.

In order for this to be done, a field study using the formulated product, and characteristic rotational crops is needed to identify the residues for which tolerance must be set. The applicant is referred to CFR 46: 3018 January 13, 1981 for the changed Agency policy towards rotational crops.

B. Orange Grapefruit uses

1. See A-5
2. See A-2
3. See A-3
4. EPA comment: EFB requests clarification on the leaching study (accession no. 099248, page 00014) as to the length of the leaching column and the acre-inch equivalents of water used.

Applicant response: The column length was 5 cm and 80 acre inches of water were used.

EPA response: Proposed Guidelines suggest the use of a 20 cm column eluted with 20 acre-inches of water. Original EFB conclusions that the leaching study is unsuitable remain. A valid leaching study designed as suggested by the proposed 1978 Guidelines is required for the proposed use. DAC-3701 and chlorothalonil must both be studied.

5. EPA comment: A soil degradation product of chlorothalonil, DAC-3701 is persistent and mobile in soil. A groundwater monitoring study is needed for the citrus use.

Applicant response: The previously submitted study "Evaluation of Leaching of Chlorothalonil under Field Conditions..." noted no residues of DS-3701 (sic) in groundwater under field conditions.

EPA response: The mobility of DS-3701 appears to be based on the previously discussed (see B.4.) laboratory leaching study which used insufficient soil and excessive water. The cited applicant submission does indeed show that a DS-3701 was not detected in ground water in a sandy soil with relatively low organic matter content. study until a valid laboratory leaching study is submitted for review (see B.4.), at which time the need for a monitoring study will be reevaluated.

Something is missing here

6. See A.4. Also, the need for a groundwater monitoring study will be deferred pending submission of a valid laboratory leaching study.

3.0 Recommendations

EFB concurs with the applicant that the field dissipation of chlorothalonil is sufficiently well-defined by previously submitted and reviewed studies. Also, the need for a groundwater monitoring study will be deferred pending submission of a valid laboratory leaching study. In all other instances, however, EFB could not agree with the applicant's arguments. Therefore, with the exception of field dissipation discussed above in 2.A.2. and 2.B.2, and the need for a groundwater monitoring study, EFB maintains its concerns and conditions for registration of chlorothalonil on soybeans and on grapefruit and oranges.



Henry Appleton
Chemist
Section 1/EFB



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

OCT 30 1980

Diamond Shamrock Corporation
Agricultural Chemicals Division
1100 Superior Avenue
Cleveland, OH 44114

OCT 30 1980

Attention: Mr. J. R. Lucietta

DIAMOND SHAMROCK CORPORATION
AGRICULTURAL CHEMICALS DIVISION

Gentlemen:

Subject: Bravo 500
EPA Registration No. 677-313
Applications Received February 19 and September 3, 1980

Your applications to amend the registration of the subject pesticide product by adding use patterns for use on soybeans and for use on oranges and grapefruit have had certain data reviewed. We find it appropriate to communicate the deficiencies identified during these reviews. Registration of the proposed use-patterns must await completion of all data reviews and the establishment by regulation of appropriate tolerances for residues that may result from those proposed use-patterns. The following data deficiencies must be addressed prior to registration of these proposed use patterns:

Ecological Effects Data

Because of its extreme toxicity, its relative persistence and the lack of information on its behavior in the environment, additional studies are needed to assess the increased hazards to fish and wildlife from the additional use of chlorothalonil on soybeans. The following tests and analyses are required:

1. An aquatic invertebrate life-cycle study using technical grade chlorothalonil.
2. An avian dietary toxicity test on two avian species, one species of wild waterfowl (mallard) and one species of upland game bird (bobwhite quail) using the metabolite DS-3701.
3. Residue analysis (for chlorothalonil and DS-3701) of mammal and avian food items (plant, insect, etc.) in habitats in and adjacent to treated areas. These analyses must be obtained under typical use conditions.
4. Aquatic field research that will include but is not limited to:
 - a) Analyses of water (filtered and unfiltered) and sediment samples for the presence of chlorothalonil and DS-3701 under conditions that would maximize runoff and leaching.

The drainage basin of choice should have:

1. 1-5% slope;

- i: Soil types which have previously been studied in laboratory absorption-desorption tests; and
- iii A single continuously-flowing channel draining the entire basin. If possible the channel should be monitored by the U.S.G.S. or some other experienced agency.

These studies must include samples from:

- i Surface runoff;
- ii Receiving waters, where the treated field drains into a permanent or natural water system;
- iii The drainage water (include a description of system monitored);
- iv Leachate and groundwater in or adjacent to target area if possible; and
- v The soil of the treated area to determine how much chlorothalonil and DS-3701 is remaining in the soil to be released over an extended period of time.

Parameters to be monitored during this field study are:

- i Continuous rainfall;
 - ii Continuous temperature;
 - iii Runoff per rainfall event;
 - iv Concentration of pesticide in runoff at each rainfall event;
 - v Concentration of sediment by weight (total kg/runoff event)
 - vi Percent soil cover by month; and
 - vii Daily pan evaporation.
- b. Studies that will address the potential adverse effects on non-target aquatic species. This may include examination of caged organisms and or natural aquatic populations adjacent to treated areas.

Environmental Fate - Soybeans

The fate of chlorothalonil in the environment has not been sufficiently described to support the proposed soybean use. The following data requirements have not been fully satisfied:

1. Anaerobic soil metabolism - An anaerobic soil metabolism study using soil aged at 25°C will be required.
2. Field dissipation - Such data were previously submitted and reviewed in our evaluation of PP 1F 1024 dated July 15, 1971. Field dissipation of the parent compound was shown but analysis was for parent compound only and soil profiles were not provided. Field dissipation data are needed as described in the July 10, 1978 Proposed Guidelines, sections 163.62-10(a) and 163.62-10(b)(1).
3. Catfish accumulation study - According to the July 10, 1978 Proposed Guidelines, sections 163.62-11(a) and 163.62-11(d), these data are needed.
4. Effects of the pesticide on microbes - The submitted data satisfied this requirement in part. The deficiencies were ~~tested~~ tested in this Agency's June 29, 1978 letter addressed to you. 2h6
10-24-
5. With regard to the soil absorption/desorption study, we note the soil was sieved at 60 mesh which removed large sand particles. We would expect this to result in higher K values than expected if such fine sieving had not been done. How do you anticipate the sieving done in this study affected the K values derived compared to the K values that would be derived if sieving were not done?
6. The laboratory rotational crop data show the need for an 18 month crop rotational restriction in that ¹⁴C residues are present in the rotational crop at the tested rotational interval. To remove the 18 month crop rotation restriction, rotational crop data acquired under actual field use conditions are needed. These data must show no detectable residues at the desired rotational interval. These field data must be compared to the lab ¹⁴C data. Refer to the Proposed Guidelines, sections 163.62-11(a) and 163.62-11(b).

To enable review of the field rotational crop data, the following questions must be answered: What is the nature of the water soluble ¹⁴C residues found in the lab ¹⁴C rotational crop study? How many compounds are in this water soluble fraction? Is the benzene ring intact in these compound(s)? Would or would not these residues be expected to be found in crops grown in non-radio-labeled chlorothalonil fortified soil and why?

Environmental Fate - Oranges and Grapefruit

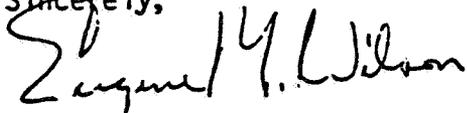
The following data gaps exist for the orange and grapefruit use.

1. With regard to the soil absorption/desorption study, we note the soil was sieved at 60 mesh which removed large sand particles. We would expect this to result in higher K values than expected if such fine sieving has not been done. Do you predict the sieving done in this study affected the K values derived compared to the K values that would be derived if sieving had not been done?

2. Field dissipation - Such data were previously submitted and reviewed in our evaluation of PP 1024 dated July 15, 1971. Field dissipation of the parent compound was shown but analysis was for parent compound only and soil profiles were not provided. Refer to the July 10, 1978 Proposed Guidelines for sample protocol.
3. Catfish accumulation study - Refer to the July 10, 1978 Proposed Guidelines for sample protocol.
4. In the leaching study in accession number 099248, page 000114, what is the length of the leaching column and how many acre - inch equivalents of water were used for leaching?
5. The soil degradation product of chlorothalonil, DAC 3701, is persistent and mobile in soil. Groundwater contamination is a possibility especially since the proposed citrus use areas may be in sandy soil areas. A groundwater monitoring program is needed.
6. Effects of the pesticide on microbes. Data previously reviewed satisfy this requirement in part. The deficiencies were listed in this Agency's June 29, 1978 letter addressed to you.

We received the protocols submitted under your letter of June 26, 1980. We assume that you have studies underway that will resolve the data deficiencies mentioned above.

Sincerely,



Eugene M. Wilson
Acting Product Manager (21)
Fungicide-Herbicide Branch
Registration Division (TS-767)

Response to EPA Letter 10/30/80

APPENDIX II

RESPONSE TO
EPA LETTER DATED OCTOBER 30, 1980

CHLOROTHALONIL (BRAVO 500)
EPA Registration No. 677-313
Applications Received
February 19 and September 4, 1980
PP Nos. 6F1799, 0F2405 and 0H5272
Soybeans; Oranges and Grapefruit

ENVIRONMENTAL FATE - SOYBEANS

1. COMMENT

Anaerobic soil metabolism - An anaerobic soil metabolism study using soil aged at 25°C will be required.

RESPONSE

An anaerobic soil metabolism study was conducted and submitted in the report "Degradation of Daconil and Its Metabolite, 4-Hydroxy-2,5,6-Trichloroisophthalonitrile, in Soil. Part I: Degradation Under Greenhouse Conditions. Part II: Anaerobic Soil Metabolism of Daconil."

This study was submitted in Section J, PP 6F1749, Volume VIII, pp 111 to 176, submitted February 25, 1976. This study was also cited in the Tabular Summary of References and submitted in Section J of both the initial application and amendment dated May 25, 1976 and February 19, 1980, respectively, PP 6F1799.

In this study five soil types were fortified with ¹⁴C-chlorothalonil, aged under greenhouse conditions (27°C to 35°C) and stored under anaerobic conditions. There was no significant difference in metabolism under aerobic and anaerobic conditions.

2. COMMENT

Field dissipation - Such data were previously submitted and reviewed in our evaluation of PP 1F1024 dated July 15, 1971. Field dissipation of the parent compound was shown but analysis was for parent compound only and soil profiles were not provided. Field dissipation data are needed as described in the July 10, 1978 Proposed Guidelines, sections 163.62-10(a) and 163.62-10(b)(1).

RESPONSE

In the study "Evaluation of the Leaching of Chlorothalonil under Field Conditions and Its Potential to Contaminate Underground Water Supplies" (see APPENDIX III) the dissipation of chlorothalonil and DS-3701 was determined under field conditions. The 3 acre sandy loam test area was treated with 3 pounds chlorothalonil per acre at weekly intervals for five consecutive weeks. After each weekly application and for seven consecutive months residues of chlorothalonil and DS-3701 were determined in soil profiles taken in 3 inch increments to a depth of 12 inches. Results of this study showed that neither chlorothalonil nor DS-3701 accumulated in the soil. Chlorothalonil did not leach and remained in the upper 3 inches of the soil. The residue of chlorothalonil did not exceed the theoretical concentration (1 pound per acre is equivalent to approximately 1 ppm in a 3 inch acre).

In laboratory studies it was shown that chlorothalonil has a half-life of 5 days in the sandy loam soil used in the field study. Because of this rapid degradation chlorothalonil did not accumulate in this soil.

The adsorption of chlorothalonil onto this soil was also determined under laboratory conditions. This sandy loam soil had a relatively low adsorption capacity for chlorothalonil and would have had a greater potential for leaching of chlorothalonil than other soil types tested. Under field conditions, however, no significant residues of chlorothalonil were detected below the 0 to 3 inch increment.

Response to EPA Letter 10/30/80

3. COMMENT

Catfish accumulation study - According to the July 10, 1978 Proposed Guidelines, sections 163.62-11(a) and 163.62-11(d), these data are needed.

RESPONSE

This study was experimentally completed in accordance with the following previously submitted protocols (originally submitted in Section J February 19, 1980, resubmitted June 26, 1980). These reports will be completed by April, 1981.

Residue Accumulation Study in Channel Catfish with ^{14}C -2,4,5,6-Tetrachloroisophthalonitrile (Chlorothalonil) under Static Conditions (document number RM-78-0032)

Characterization of ^{14}C -Residues in Water, Soil and Fish Exposed to ^{14}C -2,4,5,6-Tetrachloroisophthalonitrile (Chlorothalonil, DS-2787) in a Static Aquatic System (document number 078-3EI-79-0030-000)

4. COMMENT

Effects of the pesticide on microbes - The submitted data satisfied this requirement in part. The deficiencies were listed in this Agency's June 29, 1978 letter addressed to you.

RESPONSE

These studies were experimentally completed in accordance with the following previously submitted protocols (originally submitted in Section J February 19, 1980, resubmitted June 26, 1980).

Reports for these studies will be completed by April, 1981.

Effect of 2,4,5,6-Tetrachloroisophthalonitrile (Chlorothalonil, DS-2787) upon Nitrogen Transformation in Soil (document number 328-3EI-79-0011-000)

Effect of 2,4,5,6-Tetrachloroisophthalonitrile (Chlorothalonil, DS-2787) upon Non-Symbiotic Nitrogen Fixing Soil Microorganisms (document number 327-3EI-79-0010-000)

Effect of 2,4,5,6-Tetrachloroisophthalonitrile (Chlorothalonil, DS-2787) upon the Microbial Utilization of Selected Macromolecules in Soil (document number 326-3EI-79-0009-000)

Effect of 2,4,5,6-Tetrachloroisophthalonitrile (Chlorothalonil, DS-2787) upon Soil Dehydrogenase Activity (document number 329-3EI-79-0012-000)

Response to EPA Letter 10/30/80

5. COMMENT

With regard to the soil adsorption/desorption study, we note the soil was sieved at 60 mesh which removed large sand particles. We would expect this to result in higher K values than expected if such fine sieving had not been done. How do you anticipate the sieving done in this study affected the K values derived compared to the K values that would be derived if sieving were not done?

RESPONSE

The soil used for the adsorption study was sieved at less than 500 microns to remove stones, large plant fragments and coarse sand as specified in the proposed EPA Guidelines for Registering Pesticides. The sieving was conducted for all soils used in the test, thereby introducing uniformity into the experimental design. Adsorption is a characteristic of soil type. The soil type is independent of aggregate size. Sieving does not, therefore, alter the adsorption characteristics of the soil and had little, if any, effect upon the K values obtained in the study.

5. COMMENT

The soil degradation product of chlorothalonil, DAC-3701, is persistent and mobile in soil. Groundwater contamination is a possibility especially since the proposed citrus use areas may be in sandy soil areas. A groundwater monitoring program is needed.

RESPONSE

In the study "Evaluation of the Leaching of Chlorothalonil under Field Conditions and Its Potential to Contaminate Underground Water Supplies" (See APPENDIX III), a sandy loam field plot was treated with 3 pounds chlorothalonil per acre at weekly intervals for five consecutive weeks. Groundwater and water from an adjacent stream were sampled for seven succeeding months and analyzed for chlorothalonil and DS-3701. No residues of DS-3701 were detected in the stream water or groundwater.

Response to EPA Letter 10/30/80 .

6. COMMENT

Effects of the pesticide on microbes - Data previously reviewed satisfy this requirement in part. The deficiencies were listed in this Agency's June 29, 1978 letter addressed to you.

RESPONSE

These studies were experimentally completed in accordance with the following previously submitted protocols (originally submitted in Section J February 19, 1980, resubmitted June 26, 1980). Reports for these studies will be completed by April, 1981.

Effect of 2,4,5,6-Tetrachloroisophthalonitrile (Chlorothalonil, DS-2787) upon Nitrogen Transformation in Soil (document number 328-3EI-79-0011-000)

Effect of 2,4,5,6-Tetrachloroisophthalonitrile (Chlorothalonil, DS-2787) upon Non-Symbiotic Nitrogen Fixing Soil Microorganisms (document number 327-3EI-79-0010-000)

Effect of 2,4,5,6-Tetrachloroisophthalonitrile (Chlorothalonil, DS-2787) upon the Microbial Utilization of Selected Macromolecules in Soil (document number 326-3EI-79-0009-000)

Effect of 2,4,5,6-Tetrachloroisophthalonitrile (Chlorothalonil, DS-2787) upon Soil Dehydrogenase Activity (document number 329-3EI-79-0012-000)

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