

US EPA ARCHIVE DOCUMENT



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

MAY 22 1991

MEMORANDUM:

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: NE-900004; 24(c). Chlorothalonil (Bravo 720, EPA Reg. No. 50534-188) on dry beans.
MRID No. 418441-00 (Transmittal) and -01 (Residue study)
DEB No. 7931. DP Barcode No. D163742.

FROM: John Abbotts, Chemist *John Abbotts*
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division [H7509C]

THRU: Francis B. Suhre, Section Head *Francis B. Suhre*
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division [H7509C]

TO: Susan Lewis/James Stone, PM-21
Fungicide-Herbicide Branch
Registration Division [H7505C]

The State of Nebraska has submitted residue data to support a Section 24(c) registration for the use of the fungicide Bravo® 720 (chlorothalonil) on dry beans with a 14 day PHI. Previously CBRS had recommended against this 24(c) registration (D. McNeilly Memoranda, 10/23/90 and 2/26/91) because residue data indicated that the existing tolerance for chlorothalonil (tetrachloroisophthalonitrile) and its 4-hydroxy metabolite (4-hydroxy-2,5,6-trichloroisophthalonitrile) in or on dry beans may be exceeded as a result of the proposed use. The assignment instructions are to evaluate the response to D. McNeilly's review of 2/26/91.

Bravo 720 contains 54% chlorothalonil (0.75 lb ai/pint). Trace amounts of hexachlorobenzene (HCB) and pentachlorobenzonitrile (PCBN) can sometimes be found in this formulation. Both of these impurities were analyzed in the residue data submitted with this Section 24(c) request. No HCB (<0.003 ppm) or PCBN (<0.005 ppm) were found in any sample analyzed.

A chlorothalonil Registration Standard and Reg. Std. FRSTR have been issued. The FRSTR is dated Feb 19, 1988.

A tolerance has been established for the combined residue of the parent, chlorothalonil (2,4,5,6-tetrachloroisophthalonitrile) and



DEB 7931, Chlorothalonil Section 24, p. 2

its metabolite (4-hydroxy-2,5,6-trichloroisophthalonitrile) in or on dry beans at 0.1 ppm (40 CFR 180.275).

Proposed Use

The proposed use calls for an initial treatment during the early bloomstage using 1-3/8 to 2 pints of Bravo 720 (1.03 to 1.5 lb ai) per acre per application, treatment may be repeated at 7 to 10 day intervals. Use would be restricted to beans harvested with the pods removed. Do not apply within 14 days before harvest. Do not allow livestock to graze in treated areas or feed treated plant parts to livestock.

The currently registered use for chlorothalonil on dry beans (harvested dry with pods removed) allows for 2 pints of Bravo 720 (1.5 lb ai) per acre per application. Applications can begin during early bloom stage and repeat at 7 to 10 day intervals. Do not apply within 42 days of harvest. Do not graze treated areas or feed treated plant parts to livestock.

In summary, the State of Nebraska wants to reduce the PHI to 14 days from the currently authorized 42 day PHI for chlorothalonil in or on dry beans. The stated reason for this request is that a 42 day PHI does not provide adequate protection against late-season epidemics of rust (Uromyces phaseoli) and other foliar diseases of dry beans.

Background

On several occasions, CB (or RCB or DEB) has recommended against a 14 day PHI for chlorothalonil on dry beans:

RCB expressed concern with a 14 day PHI over data submitted with PP8E2065 where residues on dry beans exceeded 0.1 ppm. From these residue data, RCB recommended a tolerance of 0.1 ppm provided the petitioner limit the use to 3 applications of 1.5 lb ai per acre per application and increase the PHI from the originally proposed 14 days to 6 weeks (PP8E2065, P.V. Errico, 5/15/81).

In 1984, SDS Biotech Corporation requested a Section 24(c) registration which would reduce the PHI to 14 days when using chlorothalonil on dry beans in the state of North Dakota. In reviewing this request, RCB noted the previous residue data submitted with PP8E2065, and concluded that the 0.1 ppm tolerance on dry beans would be exceeded as a result of unlimited applications of chlorothalonil and reducing the PHI to 14 days. RCB recommended against the 24(c) registration (PP8E2065, L.S. Propst, 7/9/84 and 12/18/84).

In 1990, the Nebraska Department of Agriculture issued a Section 24(c) registration for the use of chlorothalonil in or on dry

beans, under which the PHI was reduced to 14 days. No residue data were submitted with this Section 24(c), and DEB referred to the residue data previously submitted under PP8E6065. DEB concluded that the data available did not support decreasing the PHI to 14 days, and recommended against the 24(c) registration; DEB noted it would reconsider the recommendation upon receipt of adequate residue data to support the proposed use (NE-900004, D. McNeilly, 10/23/90).

The state of Nebraska subsequently submitted residue data from two different field trials to support the Section 24(c) registration. The results of the first trial are reproduced below as reported (NE-900004, D. McNeilly, 2/26/91).

Table No.	PHI, days	Number of applications	Pints applied/application	Residue range, ppm
5	43	2	2 (0.7X)	ND-0.08
6	43	2	3 (1.04X)	ND-0.09
6	43	2	4 (1.4X)	ND-0.19
7	40	3	2 (0.7X)	ND-0.08
8	40	3	4 (1.4X)	ND-0.08
9	28	3	4 (1.4X)	ND
10	27	1	3 (1.04X)	ND

Table 1. Residues of chlorothalonil and its 4-hydroxyl metabolite in or on dry beans (pods removed).

Table note: Table No. refers to the original table in Diamond Shamrock Corp. report 463-3CR-81-0154-001.

Numbers in parentheses under the pints applied column in Table 1 indicate that some field trials applied Bravo-500, which contains a lower proportion of ai per pint (0.7X) than Bravo-720 (1.04X), the formulation for which the Section 24(c) registration was requested. 3 pints of Bravo 500 yield approximately the same amount of ai as 2 pints of Bravo 720. In reviewing these data, CB noted that there are four instances where the residue approaches the tolerance level, and one where it exceeds it. These data are for PHIs longer than 14 days, and the conclusion from these data was that the residue with unlimited applications and a PHI of 14 days was very likely to exceed the 0.1 ppm tolerance for chlorothalonil and its 4-hydroxy metabolite in or on dry beans (NE-900004, D. McNeilly, 2/26/91).

The state of Nebraska at the same time submitted data from a second set of field trials. The results from these field trials are reproduced below as reported (D. McNeilly, 2/26/91):

Table No.	PHI, days	Number of applications	Pints applied/ application	Residue range, ppm
5	14	3	2(0.7X)	ND-0.03
5	14	3	3(1.04X)	ND-0.03
6	0	5	3(1.04X)	ND-0.07
6	8	4	3(1.04X)	ND-0.03
7	13	4	3(1.04X)	ND
9	7	5	3(1.04X)	ND-0.04
9	14	4	3(1.04X)	ND-0.01
10	9	4	3(1.04X)	ND-0.03

Table 2. Residues of chlorothalonil and its 4-hydroxy metabolite in or on dry beans (pods removed).

Table note: Table number refers to the original Table number in Diamond Shamrock Corp. report 612-3CR-82-0181-001.

In reviewing these data, CB noted that they suggest that the tolerance would not be exceeded. However, review of the data submitted indicated that each data point consists of one sample and its duplicate. The previous study (Table 1), which represented longer PHIs, contained significantly more data points. The data in the first report indicate that the tolerance may be exceeded. In addition, CB referred to the previous field trial data which indicated that a 0.1 ppm tolerance would not be adequate to cover all residues resulting from a PHI of 14 days (PP8E2065, P.V. Errico, 5/15/81). CBRS did not consider the limited residue data submitted in Table 2 to be sufficient to support lowering the PHI from 42 to 14 days. CBRS noted that the data submitted did not change the concern that the tolerance may be exceeded as a result of the proposed use, which included unlimited applications, and therefore continued to recommend against this 24(c) registration. CBRS indicated that it would reconsider this recommendation upon receipt of residue data clarifying the discrepancies between the two data sets (dry beans) indicated in Tables 1 and 2. (D. McNeilly, 2/26/91)

Present Submission

In response to the CB review of 2/26/91, the State of Nebraska submitted a report on residue data, "Determination of residues of chlorothalonil (SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN in Crops: Dry Beans." (MRID No. 418441-01 for the report, -00 for the transmittal letter). Field trials were conducted at four locations in North Dakota, Nebraska, Michigan, and Colorado. Residue data from these trials are summarized in the table below:

Location	Applica- tions	Bravo Product, ai/A	PHI, days	Residue range, ppm	
				SDS-2787	SDS-3701
No. Dak.	8	720, 1.5 lb	14	ND	ND
NE	3	720, 1.5 lb	14	ND	ND-0.016
MI	4	720, 1.5 lb	14	ND	ND
CO	2	720, 1.5 lb	18	ND	0.012
CO	2	C/M, 1.08 lb	18	ND	ND

Table 3. Residues of chlorothalonil (SDS-2787) and its 4-hydroxy metabolite (SDS-3701) in or on dry beans (pods removed).

Table notes: ND is <0.01 ppm for SDS-2787 and SDS-3701.

In addition to the samples above, the data were also provided for residues on SDS-46851, a soil metabolite of chlorothalonil; hexachlorobenzene; and pentachlorobenzonitrile. Residues for these chemicals for all samples were below the limits of detection, which were <0.03, <0.003, and <0.005, respectively. Bravo C/M is a formulation of chlorothalonil in combination with copper and maneb.

These data suggest that tolerances would not be exceeded. However, except for the field trials in North Dakota, trials are limited to 2-4 applications, conditions which do not address the concern that applications would be unlimited under the Section 24(c) proposed use. Moreover, each data set represents duplicate laboratory determinations of single samples. This is the same type of data as that represented in Table 2, and does not explain why earlier residues were so high. The previous review desired data clarifying the discrepancies between the residue samples of Tables 1 and 2 (D. McNeilly, 2/26/91). The cover letter from the

5

state of Nebraska contains a conclusory statement that the most recent set of residue data "will clarify any questions regarding potential residue problems" (MRID 418441-00). However, neither the submitted report nor the cover letter provides information that would resolve the discrepancies between the data in Table 2 with those in Table 1 nor residue data submitted with PP8E2065.

In summary, this latest data submission is also not sufficient to support lowering the PHI from 42 to 14 days.

Conclusions

Since 1981, CB has on several occasions recommended against reducing the PHI for chlorthalonil on dry beans from 42 to 14 days. There is no prohibition on changing this position, but the concerns previously expressed will have to be adequately resolved. Two major issues have been of concern:

--That residue data previously submitted indicate that the tolerance of 0.1 ppm for chlorothalonil and its 4-hydroxy metabolite in or on dry beans would be exceeded if the PHI is reduced from 42 to 14 days.

--That unlimited applications would be allowed under the proposed use that would reduce the PHI.

With regard to the second concern, a representative of SDS Biotech Corporation in 1984 wrote:

"[S]ince it would not be economically feasible for a grower to make more than three applications of BRAVO on dry beans, we would not oppose going back to these states and adding this restriction to alleviate the Agency's concern." (Chlorothalonil Section 24(c) file, R.P. Burton, SDS Biotech Corporation, letter to H.M. Jacoby, Fungicide-Herbicide Branch, U.S. EPA, July 13, 1984.)

Limiting the number of applications to 3 would be a first step in addressing the concerns of CBRS. Nonetheless, petitioners would still have to submit detailed residue data to indicate that tolerances would not be exceeded under the proposed use, and would have to resolve discrepancies with previously submitted residue data. Submitting duplicate laboratory determinations of a single sample from a field test is not sufficient to meet these concerns.

Residue data for this Section 24(c) registration were generated by Hazleton Laboratories; no data were generated by Craven Laboratories.

Recommendation

Since 1981, CB and its predecessor branches have taken the position that the 0.1 ppm tolerance for chlorothalonil and its 4-hydroxy metabolite in or on dry beans may be exceeded as a result of unlimited treatments and a PHI of 14 days. The residue data submitted do not change the concern that the tolerance may be exceeded as a result of the proposed use.

Therefore, CBRS continues to recommend against this 24(c) registration. CBRS is willing to reconsider this recommendation upon receipt of residue data clarifying the discrepancies between the data sets discussed in this review in Tables 1, 2, and 3.

We further recommend that a copy of this review be furnished to Mr. Rich Reiman, Director, Bureau of Plant Industry, Nebraska Department of Agriculture.

cc: Circ; Abbotts; 24(c) File; RF; Chlorothalonil SF;
PIB/FOD (C.Furlow)
RDI:FBS:5/17/91:EZ:5/19/91
H7509C:CBII-RS:JAbbotts:CM-2:Rm812a:5/21/91