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

MAY 30 1986

Memorandum

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: Ridomil®/Bravo 81W (Metalaxyl/Chlorothalonil)
Use on Cole Crops and Potatoes.
EPA Reg. No. 100-ALI
RCB #746

From: Michael S. Metzger, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Thru: Edward Zager, Section Head, SRS 2
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

To: Henry M. Jacoby, PM 21
Registration Division (TS-767C)

Ciba-Geigy Corporation submits a cover letter and revised labeling in response to a letter (11/26/85) from Henry M. Jacoby, PM 21, stating deficiencies which must be resolved prior to registration of their product, Ridomil®/Bravo 81W (metalaxyl, 9.0%; chlorothalonil, 72.0%; inert ingredients, 19%) for use on potatoes. All inerts in this formulation are cleared under 40 CFR 180.1001 (see confidential appendix). The deficiencies will be stated below followed by the submitter's reply and RCB's comments/conclusions.

In addition to this, Ciba-Geigy requests amended registration allowing application of Ridomil®/Bravo 81W to the cole crops broccoli, cabbage and cauliflower. This proposed use has not been previously addressed and will be discussed following comments made regarding use on potatoes.

Deficiencies #1 and #2

1) Some discrepancies exist between the proposed labeling for this product and the currently accepted labeling for the active ingredients alone for the use on potatoes. Make appropriate labeling changes or submit justification for the differences.

2) The currently accepted label for Ridomil 2E contains a pre-harvest interval of 7 days which does not appear on the proposed label. Also, the proposed label states that the product should not be applied more frequently than every 14 days but the proposed label recommends a 7-day interval for severe disease conditions.

Submitter's Response

Regarding point #2, the labeling enclosed has been revised to include a Note prohibiting application to potatoes within 7 days of harvest. Regarding the second point of point #2, it is true the Ridomil 2E label originally accepted for use on potatoes stated the product should not be applied more frequently than every 14 days for control of late blight. The 7-day interval proposed on the Ridomil®/Bravo 81W label refers to control of early blight and botrytis vine rot, which are diseases primarily controlled by chlorothalonil, not metalaxyl. A 7-10 day interval is recommended on the currently registered Bravo label, with the shorter interval used for severe disease pressure. Typically, potatoes are a 90-day crop. Application of Ridomil®/Bravo 81W either on a 14-day schedule at up to 2 lbs./A or on a 7-day schedule at up to 1 1/2 lbs./A will not cause metalaxyl rates to exceed the maximum total application of 2.25 lbs. a.i./A as currently registered. Also, the 7-day interval is currently recommended for severe disease pressure and it is not likely all applications during the season would be made at that interval. Therefore, we have elected not to change this portion of the label.

RCB's Comments/Conclusions

The Table below shows the application schedules and maximum application rates of Ridomil®/Bravo 81W, Ridomil® 2E and Bravo® 500. Included are the maximum application rates, the intervals between applications, the PHI's, the maximum number of applications and the total lbs.a.i./A/season assuming a 90-120 day growing season (DGS).

Ridomil®/Bravo 81W Application Rates vs. Registered Application Rates for Pesticides Containing the Individual Active Ingredients to Potatoes

Formulation	Max. Application Rate (lbs.a.i./A)	Total lbs.a.i./ A/Season (90-120 DGS)	Max. No. Applications (Interval)	PHI
Ridomil®/Bravo 81W:				
Metalaxyl	0.18	1.08- 1.44	6- 8 (14)	7
	0.135	1.62- 1.30	12-17 (7)	7
Chlorothalonil	1.44	8.64-11.52	6- 8 (14)	7
	1.08	12.96-18.36	12-17 (7)	7
Ridomil® 2E:				
Metalaxyl	0.25	1.5- 2.0	6- 8 (14)	7
Bravo 500W:				
Chlorothalonil	1.11	13.32-18.86	12-17 (7)	0

Ciba-Geigy has complied with the inclusion of a 7-day PHI on the label. However, Ciba-Geigy elected to retain the 7-day interval between applications as they discuss above. RCB has reviewed residue data previously submitted by Ciba-Geigy for applications of metalaxyl to potatoes. The data are summarized in the table below (PP#1F2500, Acc. No. 070020).

Metalaxyl Residues on Potatoes

Application Rate (lbs.a.i./A)	Number of Applications	Total Lbs.a.i./A	PHI	Metalaxyl Residue Range (ppm)
0.25	3-6	0.75-1.50	1	<0.05
"	"	"	7	<0.05
"	"	"	14	<0.05
0.375	3-6	1.125-2.25	7	<0.05-0.49
"	"	"	14-15	0.07-0.21
"	"	"	24-31	<0.05-0.08
0.50	6	3.0	11	0.14
"	"	"	28	0.07
0.75	6	4.5	24	0.08-0.14
1.0	6	6.0	11	0.28
"	6	"	28	0.33
1.14	6	6.84	29	0.17-0.18

Application at a rate of 0.375 lbs.a.i./A most closely approximates the proposed use rate and schedule because the total lbs. metalaxyl/A/season is close to that proposed, and because the interval between applications of 14 days for 0.375 lbs.a.i./A closely approximates intervals between applications of 7 days for 0.135 lbs.a.i./A. Statistical analysis of these data show that it is unlikely that metalaxyl residues will exceed the current 0.5 ppm tolerance on potatoes when metalaxyl is applied as it was in the residue studies. Based on analysis of the above residue data, RCB concludes that it is unlikely that the current 0.5 ppm tolerance for total residues of metalaxyl on potatoes will be exceeded as a result of the proposed use.

Chlorothalonil (Bravo 500W) is currently registered for application at a rate of 1.11 lbs.a.i./A at 7-day intervals on potatoes. Since this application rate and schedule is almost identical to the proposed use rate and schedule, RCB concludes that it is unlikely that total chlorothalonil residues in or on potatoes will exceed the current tolerance of 0.1 ppm.

RCB considers deficiencies #1 and #2 satisfied.

Deficiency #3

3) The proposed label rate exceeds the maximum dosage rate we have accepted for chlorothalonil on potatoes. Change the dosage rate so as not to apply more than 1.125 lbs. actual chlorothalonil per acre.

Submitter's Response

The currently registered chlorothalonil rate/A for potatoes is 1.125 lbs.a.i. for all diseases which can be applied at 7-10 day intervals, without the need for a pre-harvest interval. The proposed Ridomil®/Bravo 81W label calls for a maximum chlorothalonil rate of 1.44 lbs.a.i./A applied at 14-day intervals or 1.08 lbs.a.i./A applied on a 7-day schedule, with a 7-day pre-harvest interval imposed.

We would contend, then, that when applying Ridomil®/Bravo 81W on a 14-day schedule, the total amount chlorothalonil applied during the season (based on a 90-day crop) would be 6 applications times 1.44 lbs.a.i./A = 8.64 lbs.a.i. with a 7-day PHI versus 12 applications (Bravo 75W) times 1.125 lbs.a.i. = 13.5 lbs.a.i. with no pre-harvest interval. Going further, if Ridomil®/Bravo 81W were applied on a 7-day schedule, instead of 14, the total amount of chlorothalonil applied would be 1.08 lbs.a.i./A times 12 applications = 12.96 lbs.a.i./season with a 7-day PHI imposed. Therefore, the rates as proposed on the enclosed label will not exceed those currently registered for chlorothalonil on potatoes, when taking into consideration the total amount applied per acre per season and the imposition of a 7-day PHI.

RCB's Comments/Conclusions

RCB concurs with the gist of Ciba-Geigy's arguments. We would also add that since chlorothalonil is a systemic pesticide and is also persistent in the environment, the lower the total application/A/season, the lower the residues are likely to be. Therefore, RCB concludes that residues of chlorothalonil are not likely to exceed the established tolerance of 0.1 ppm in or on potatoes as a result of the proposed use.

We consider deficiency #3 satisfied.

Deficiency #4

4) For onions, the statement prohibiting use on sweet Spanish onions is no longer required for chlorothalonil. The statement may be deleted unless there is some effect from the mixture on this type of onions.

Submitter's Response

We have recently been informed about the removal of this restriction from the Bravo label. However, since we do not have data to satisfy ourselves that Ridomil®/Bravo 81W when used in conjunction with a Bravo spray program is safe, we have elected to amend this rstriction by saying, "Do not apply to sweet Spanish onions if they have received or will receive additional chlorothalonil applications."

RCB's Comments/Conclusions

RCB agrees with the submitter in that if the submitter believes that inadequate residue data are available for this use, the proposed labeling reflecting a cautious approach is reasonable.

Deficiency #4 is satisfied.

Deficiencies #5, #6 and #7

5) Reentry statements, page 4 last paragraph, delete the word "at" and use "on" after the underlined phrase precautionary statements.

6) Hazards to Humans and Domestic Animals, revise the language on using a mask or respirator to read "wear a mask or a jointly approved pesticide respirator (by the Mining Enforcement and Mining Administration and the National Institute for Occupational Safety and Health).

7) Delete "or wetlands" from the environmental hazards section.

Submitter's Response

Points #5, #6 and #7 have been addressed in the revised proposed labeling enclosed.

RCB's Comments/Conclusions

Deficiencies #5,6, and 7 have been satisfied.

Cole Crops: Broccoli, Cabbage and Cauliflower

Tolerances for combined residues of metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine, methyl ester], its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)alanine, methyl ester, range from 0.02 ppm (milk) to 20 ppm (peanut hay), and include 2 ppm for broccoli, cabbage and cauliflower (40 CFR 180.408). Tolerances for combined residues of chlorothalonil [2,4,5,6-tetrachloroisophthalonitrile] and its metabolite 4-hydroxy-

2,5,6-trichloroisonitrile range from 0.05 ppm (bananas) to 15 ppm (celery) and include 5 ppm for broccoli, cabbage and cauliflower. Several tolerances are pending (40 CFR 180.275).

Ridomil®/Bravo 81W is not currently registered for use on cole crops. Ridomil® 2E is currently registered for use on broccoli, cabbage and cauliflower at 1-2 lbs.a.i./A at planting. Bravo 500W is currently registered for application at a maximum rate of 1.17 lbs.a.i./A at 7-10 day intervals with no PHI imposed.

The proposed use for Ridomil®/Bravo 81W includes applications to broccoli, cabbage and cauliflower at rates of 0.135-0.18 lbs. metalaxyl/A and 1.08-1.44 lbs. chlorothalonil/A at 7-10 day intervals with a 7-day PHI imposed. Applications could be made using either ground or aerial equipment. No minimum total volume per acre is stipulated although the label states, "spray volume usually will range from 20-150 gallons per acre for dilute sprays and 5-10 gallons per acre for concentrate ground sprays and aerial applications." The label also prohibits application of more than 11 lbs. Ridomil®/Bravo 81W (0.99 lbs. metalaxyl, 7.92 lbs. chlorothalonil)/A/crop.

No new residue data were submitted with this amendment, and no residue data are available for application of the subject formulation to cole crops. Residue data for application of Ridomil® 2E and/or Ridomil® MZ58 to cole crops were submitted with PP#1F2500/1H5299 (Acc. No. 070019) and PP#3F2955 (Acc. No. 071918). Residue data are summarized in the tables below.

Metalaxyl Residues Resulting from Five Foliar Applications* of Ridomil 2E to Cole Crops

Commodity	Application Rate (lbs.a.i./A)	PHI	Residue Range (ppm)
Broccoli	0.25	7	0.14-0.35
	"	14	0.18-0.32
	0.50	7	0.46-0.62
	"	14	0.48-0.50
Cabbage	0.25	6-7	0.08-0.52
	"	14	0.06-0.19
	0.50	6-7	0.13-0.35
	"	14	0.12-0.26
Cauliflower	0.25	7	<0.05-0.37
	"	14	<0.05-0.52
	0.50	7	0.14-0.56
	"	14	0.10-0.44

*applications made at approximately 14-day intervals.

Metalaxyl Residues Resulting from One Initial Pre-Broadcast Ridomil® 2E Application and Zero-Seven Foliar Applications of Ridomil® MZ58 to Cole Crops

Commodity	Application Rate (lbs.a.i./A)	Number Applications	PHI	Residue Range (ppm)
Broccoli	2.0 + 1.16	1 + 5 (4)	7	0.11-1.21
"	"	"	14	0.10-1.14
	2.0 + 0	1 + 0	63	0.05-0.10
	"	"	71	0.10-0.12
	"	"	73	0.87-1.57
	"	"	108	0.22-0.34
Cabbage	2.0 + 1.16	1 + 5 (4)	7	<0.05-0.42
	"	"	14	<0.05-0.15
	2.0 + 0	1 + 0	73	<0.05-0.09
	"	"	74	<0.05-0.11
	"	"	78	<0.05
	"	"	108	0.06-0.15
Cauliflower	2.0 + 1.16	1 + 5 (6 or 7)	7	<0.05-0.81
	"	"	14	<0.05-0.61
	2.0 + 0	1 + 0	74	0.06-0.07
	"	"	87	0.15-0.57
	"	"	105	<0.05-0.05
	"	"	108	0.13-0.14

Data for total residues of chlorothalonil and its metabolite on broccoli, cabbage and cauliflower were submitted with PP#1F1024 (Acc No. 116868) and reviewed by G. J. Beusch (1/6/71). This review states that when chlorothalonil (Bravo 75WP) is applied at a rate of 1.125-2.0 lbs.a.i./A at 7-10 day intervals, residues are not likely to exceed 5 ppm in the subject cole crops.

Based on the metalaxyl residue data, RCB concludes that it is unlikely that the 2 ppm tolerance for total residues of metalaxyl on broccoli, cabbage and cauliflower will be exceeded as a result of the proposed use. Based on the previous review by G. Beusch, RCB concludes that it is unlikely that total residues of chlorothalonil will exceed the established tolerance of 5 ppm in or on broccoli, cabbage and cauliflower. In summary, RCB concludes that it is unlikely that current tolerances for residues of the active ingredients in Ridomil®/Bravo 81W in or on the subject cole crops will be exceeded as a result of the proposed use.

Meat, Milk, Poultry and Eggs

Broccoli, cabbage and cauliflower are not used a animal feeds. Therefore, it is unlikely that secondary residues of metalaxyl or chlorothalonil will be found in meat, milk, poultry and eggs as a result of the proposed use.

Conclusions and Recommendations

(1) Deficiencies #1-7 previously identified for application of Ridomil®/Bravo 81W to potatoes have been satisfied. Residues of metalaxyl and chlorothalonil are not likely to exceed the established tolerances of 0.5 ppm and 0.1 ppm respectively as a result of the proposed use on potatoes.

(2) Residues of metalaxyl and chlorothalonil are not likely to exceed the established tolerances of 2 ppm and 5 ppm respectively on broccoli, cabbage and cauliflower as a result of the proposed use.

(3) Numerous deficiencies have been identified in the chlorothalonil Registration Standard including the need for additional residue data for application of chlorothalonil to potatoes and cole crops, as well as additional plant metabolism data. These deficiencies should be addressed in accordance with statutory deadlines. However, since the proposed application rates for the active ingredients are similar to currently registered rates, these deficiencies should not preclude the issuance of this registration at this time.

RCB has no objection to this amended registration.

Attachment to: R.F., PM-21, M. Metzger, PMSD/ISB
cc:Metalaxyl (Ridomil), Chlorothalonil (Bravo), S.F., R.F., Amended Use S.F., Circu, M. Metzger, PMSD/ISB
RDI:Ed Zager:EZ:5/29/86:RDS:5/29/86
TS-769:RCB:M.Metzger:MM:Rm 814a:CM#2:5/29/86