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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum

Subject: EPA Reg. No. 100-658: Ridomil (metalaxyl)/
Bravo 81W (chlorothalonil) amendment.
MRID No. 201994; RCB No. 2728.

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To: L. Rossi, PM-21
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With this submission, CIBA-GEIGY Corp. has responded to several deficiencies cited in RCB's previous review of the proposed amendments to the Ridomil/Bravo 81 W label (see, L. Propst, Amended Registration File, memo of 3-4-87).

Ridomil/Bravo 81W, EPA Reg. No. 100-658, is a fungicide containing 9% metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester], and 72% chlorothalonil [tetrachloroisophthalonitrile] as its active ingredients.

Tolerances are established (40 CFR 180.408) for combined residues of metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)alanine methylester, each expressed as metalaxyl in or on several raw agricultural commodities, to include (but not limited to): broccoli, cabbage, and cauliflower at 2.0 ppm; green onions at 10 ppm; dry bulb onions at 3 ppm; potatoes at 0.5 ppm, and tomatoes at 1.0 ppm.

Tolerances are established (21 CFR 561.273) for metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)alanine methylester, each expressed as metalaxyl in or on several animal feed items, including (but not limited to) potato waste (dried, processed).

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Tolerances are established (40 CFR 180.275) for combined residues of the fungicide chlorothalonil [tetrachloroisophthalonitrile) and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile in or on several raw agricultural commodities, to include (but not limited to): broccoli, cabbage, cauliflower, green onions and tomatoes at 5.0 ppm; dry bulb onions at 0.5 ppm; and potatoes at 0.1 ppm.

A Metalaxyl Registration Standard was published in June 1986. The Residue Chemistry Chapters to the Chlorothalonil Registration Standard were published September 15, 1983. A Registration Standard "Chlorothalonil Firster" is currently being initiated by RCB (personal communication with W. Hazel, RCB).

No residue data were provided with this submission, however, applicable residue data have been submitted in response to data gaps cited in the Chlorothalonil Registration Standard. In addition, the registrant has submitted 5 copies of a revised label, along with correspondence (K. Stumpf, CIBA-GEIGY, to L. Rossi, RD, dated 8-18-87) in which several previously cited deficiencies are discussed. These deficiencies are restated (in the body of this memo), followed by the registrants response, and RCB's comments.

Conclusions:

1. Chlorothalonil/metabolite residues are not expected to exceed established tolerances in or on broccoli (5 ppm), cauliflower (5 ppm), and cabbage (5 ppm) as a result of this proposed amended use.
2. Chlorothalonil/metabolite residues are not expected to exceed the established tolerance in or on dry bulb onions (0.5 ppm) as a result of this proposed amended use.
3. Chlorothalonil/metabolite residues may exceed the established tolerance in or on green onions (5.0 ppm) at a PHI of less than 21 days as a result of this proposed amended use.
4. Chlorothalonil/metabolite residues are not expected to exceed the established tolerance in or on potatoes (0.1 ppm) as a result of this proposed amended use.
5. Chlorothalonil/metabolite residues are not expected to exceed the established tolerance in or on tomatoes (5.0 ppm) as a result of this proposed amended use.
6. We have previously concluded (see, L Propst memo of 3-4-87) that residues of metalaxyl will not exceed established tolerances as a result of this proposed amended use.

Recomendation

We have no objection to the proposed amended uses of Ridomil/Bravo 81W on broccoli, cauliflower, cabbage, dry bulb onions, potatoes, and tomatoes. However, before we would recommend in favor of the amended use on green onions, a 21 day PHI will have to be stipulated.

Detailed ConsiderationsDeficiency 1a.:

We are unable to conclude that the established tolerance of 5 ppm will be adequate to cover all residues of chlorothalonil and its metabolites which may occur in or on broccoli, cabbage, and cauliflower as a result of the proposed use.

Registrant's Response:

The registrant acknowledges that the proposed amendment reflects an increase in the dosage rate (proposed rate 1.44 lbs. ai./A vs. registered rate of 1.08 lbs. ai/A); but emphasizes that the increased rate will be offset by an increase in the treatment interval (from 7-10 days to 14 days) and a restriction on the maximum number (4) of applications per season. The proposed use would allow total application of 5.8 lbs. ai/A/season, a substantial reduction from the

registered dosage of 14 lbs. ai/A/season.

RCB's comments:

Chlorothalonil is registered for use on broccoli, cabbage, and cauliflower at rates of 1.07 to 1.17 lbs. ai/A, applied at 7 to 10 day intervals with a 0 day PHI stipulated.

The amended label for Ridomil/Bravo 81W, calls for application of 1 1/2 to 2 lbs. (up to 1.44 lbs. ai./A) to broccoli, cauliflower, and cabbage at 14 day intervals. Use restrictions include: 1) Do 2) to minimize the potential for residence, do not make more than 4 applications of Ridomil/Bravo 81W per crop.

Chlorothalonil residue data in or on broccoli, cabbage, and cauliflower were submitted to the Agency in connection with PP#7F0599 and PP#1F1024. Based on a review of these data (conducted in connection with the Chlorothalonil Registration Standard) the Agency concluded that the available residue data do not support the established tolerances for the combined residues of chlorothalonil and its metabolite in or on broccoli, cabbage, and cauliflower.

We acknowledge that these amendments to the label will have the cumulative effect of lowering the seasonal chlorothalonil dosage on broccoli, cabbage, and cauliflower. Furthermore, residue data submitted in connection with the Chlorothalonil Registration Standard Data Call-In, indicate that combined residues of chlorothalonil/metabolite will not exceed established tolerances of 5.0 ppm in or on broccoli, cauliflower and cabbage. Broccoli from a field study site in MI was treated with 4 applications of chlorothalonil at 1.17 lbs. ai./A and harvested 7 days after the last treatment (MRID 40183409); a chlorothalonil/metabolite residue of 2.2 ppm was found. Cauliflower from two field study sites in OR were treated with 8 applications of chlorothalonil at 1.17 lbs. ai./A and harvested 7 days after the last treatment (MRID 40000106); chlorothalonil/metabolite residues of 0.2 and 0.11 were found. The residue data provided for cabbage reflect exaggerated rates. Cabbages from a field study site in NY were treated with chlorothalonil 11 times at 1.17 lbs. ai/A (ca 2x the proposed amended seasonal dosage) and harvested on the day of the last treatment (MRID 40183411); chlorothalonil/metabolite residues of 4.99 and 5.02 ppm were found.

Based on currently available data, we conclude that deficiency 1a has been resolved.

Deficiency 3a.:

In the absence of residue data reflecting the additional treatment with chlorothalonil on green onions and no data reflecting residues of chlorothalonil on Spanish onions, we are unable to conclude that the established tolerances of 0.5 ppm in or on dry bulb onions and 5.0 ppm in or on green onions will be adequate to cover all residues of chlorothalonil and its metabolites which may occur as a result of the proposed label revision.

Registrants Response:

The registrant agrees with the Agency that the proposed label allows for a maximum of 4 applications to green onions, and that the registered label calls for a maximum of 3 applications. To alleviate this inconsistency, the use restriction on onions have been modified to read: do not make more than 3 applications to green onions per season, and to minimize the potential for resistance, do not make more than 4 applications of Ridomil/Bravo 81W to dry bulb or seed onions.

The registrant further states that, "RCB review notes that sweet Spanish onions may not be treated with chlorothalonil. However, according to the Bravo 500 label, EPA Reg. No. 50534-8, there are no restrictions on sweet Spanish onions. In fact in a letter from Mr. Henry Jacoby dated November 26, 1985, Point # 4 stated that 'For onions, the statement prohibiting use on sweet Spanish onions is no longer required for chlorothalonil.'

However, because CIBA-GEIGY did not have data ensuring that Ridomil/Bravo used in conjunction with Bravo/spray program was safe to sweet Spanish onions, the statement, 'Do not apply to sweet Spanish onions if they have or will receive additional chlorothalonil applications' was added to the label before registration. That statement remains unaltered in the proposed label under discussion."

RCB's Response:

Registered treatments of bulb onions and green onions with chlorothalonil are summarized in the Chlorothalonil Registration Standard, as follows:

"The 75% WP and 4.17 Lbs./gal FLC formulations are registered for use on dry bulb onions at < 2.25 lbs. ai/A. Treatment is by foliar application which may be made using aerial or ground equipment. Treatment intervals of 7-10 days are recommended with initial application made prior to the appearance of disease symptoms. A 7 day PHI is in effect. Applications may be repeated at 7 to 10 day intervals. Sweet Spanish onions may not be treated."

"The following chlorothalonil formulations are registered for use on green onions: 75% WP and 4.17 lb/gal FLC. Foliar applications are applied at 1.13-2.25 lbs. ai/A using aerial or ground equipment. Treatment intervals of 7-10 days are recommended with initial application made prior to the appearance of disease symptoms. A 14 day PHI is in effect. Use is limited to three applications per season."

The Ridomil/Bravo 81W label calls for application of 1 1/2 to 2 lbs. (up to 1.44 lbs. ai/A) of product to dry bulb and green onions at 7 to 14 day intervals. Use restrictions include: 1) Do not apply to sweet Spanish onions if they have received additional chlorothalonil applications. 2) Do not apply to dry bulb onions within 7 days of harvest or to green onions within 14 days of harvest or illegal residues may result. 3) do not make more than 3 applications to green onions per season. If more than 14 days remain after 3 applications of Ridomil/Bravo 81W, it is recommended that another EPA registered fungicide which does not contain chlorothalonil be used. 4) To minimize the potential for resistance, do not make more than 4 applications of Ridomil/ Bravo 81W to dry bulb or seed onions.

Note to PM: RCB requires residue data to establish tolerances on plant crops and animal species. Residues data are generally not required for specific animal subspecies and plant varieties. A tolerance on onions (dry bulb and green) is applicable to all onion varieties, including sweet Spanish onions, provided the registered uses are supported with residue data.

Residue data for chlorothalonil in or on dry bulb onions and green onions were submitted to the Agency in connection with PP#3F1382 and PP#4E1502. Based on a review of these data (conducted in connection with the Chlorothalonil Registration Standard), the Agency concluded that the available residue data do not support the established tolerances for combined residues of chlorothalonil and its metabolites in or on dry bulb onions at 0.5 ppm, or green onions at 5.0 ppm.

Residue data, recently submitted in response to the Chlorothalonil Registration Standard Data Call-In, indicate that the established tolerance for dry bulb onions at 0.5 ppm will not be exceeded as a result of this proposed amendment. Dry bulb onions from field trials in NY, CA, and TX were treated 7 to 12 times at 1.56 lbs ai/A (10.9 to 18.76 lbs. ai/A/season) and harvested 7 days after the last treatment. Chlorothalonil/metabolite residues ranged from 0.02 to 0.12 ppm (MRID 40183405 and 40000103).

Residue data, recently submitted in connection with the Chlorothalonil Registration Standard Data Call-In, indicate that the established tolerance for green onions at 5.0 ppm may be exceeded as a result of this proposed amendment. Green onions from a field trial in TX were treated 3 times with 1.33 lbs. ai/A (4.0 lbs. ai./A/ season) and harvested 14 days after the last treatment. A chlorothalonil/metabolite residue of 7.32 ppm was found. Green onions treated in the same way but harvested 21 days after the last treatment contained chlorothalonil/metabolite residues below 5.0 ppm (MRID 40183406).

We conclude that deficiency 3a has been partially resolved. In order to fully resolve deficiency 3a, the label needs to stipulate a 21 day PHI for green onions treated in accordance with the directions appearing on the Ridomil/Bravo 81 amended label.

Deficiency 4a.:

In the absence of residue data reflecting the proposed increased application rate of chlorothalonil on potatoes, we are unable to conclude that the established tolerance of 0.1 ppm to cover residues of chlorothalonil in or on potatoes will be adequate.

Registrant's Response:

The label under discussion does not propose new rates for either potatoes or tomatoes. These rates were accepted on June 13, 1986 when Ridomil/Bravo 81W was registered. Please refer to Residue Chemistry Review Dated November 26, 1985 and subsequent CIBA-GEIGY response dated January 7, 1986 for discussion. Because these rates have already been reviewed and accepted by the Agency and are not considered to be part of the proposed amendments submitted with the label under discussion, the conclusions drawn by the Agency are questionable.

RCB's Response:

Registered uses of chlorthalonil are summarized in the Chlorothalonil Registration Standard, as follows:

"The 75% WP, 4.17 lb/gal FIC, and 12.5% FIC formulations on are registered for foliar application on potatoes at 0.75 to 1.13 lbs. ai/A, 0.59 to 1.13 lbs. ai/A, and 1.0 lb ai/A, respectively. Applications are made when the disease first appears, or when plants reach a height of 6-8 inches, at intervals of 7 to 10 days as needed. Application may be made using ground or aerial equipment. No PHI is in effect."

The Ridomil/Bravo 81W label calls for application of 1 1/2 to 2 lbs. (up to 1.44 lbs. ai/A) to potatoes at 14 day intervals. Use restrictions include: 1) Do not apply within 7 days of harvest, or illegal residues may result. 2) To minimize the potential for resistance, do not make more than 4 applications of Ridomil/Bravo 81W per crop.

Chlorothalonil residue data in or on potatoes were submitted to the Agency in connection with PP#7F0599, PP#9F0743, and PP#6F1749. Based on a review of these data (in connection with the Chlorothalonil Registration Standard), the Agency concluded that the available residue data do not support the established tolerances for combined residues of chlorothalonil and its metabolites in or on potatoes.

The registrant's assertion, that the Agency has previously recommended in favor of the proposed use of Ridomil/Bravo 81W on potatoes is correct. In a review dated 5-30-87 (see, M. Metzger, Ridomil/Bravo 81W S. F.) RCB concluded:

"Chlorthalonil (Bravo 500W) is currently registered for application at a rate of 1.11 lbs. ai/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 chlorthalonil residues in or on potatoes will exceed the current tolerance of 0.1 ppm"

The above conclusion was based on fact, that even though the amended application rate is slightly higher (per application), the total amount applied per season is lower (due to a longer interval between application).

Residue data, recently submitted in response to the Chlorothalonil Registration Standard Data Call-In, indicate that the established tolerance for potatoes at 0.1 ppm will not be exceeded as a result of this proposed amendment. Potatoes from field trials in OR, ME, OH, and WA were treated 7 to 11 times with chlorothalonil at up to 1.04 lbs. ai/A (maximum of 11.46 lbs. ai/A/season) and harvested 7 days after the last treatment. No chlorothalonil residues were found (MRID 40183403 and 40000102).

We conclude that deficiency 4a is resolved.

Deficiency 5a.:

Lacking adequate residue data, we are unable to conclude that the established tolerance of 5 ppm will be high enough to cover all residues of chlorothalonil and its metabolites on tomatoes.

Registrants Response:

The label under discussion does not propose new rates for either potatoes or tomatoes. These rates were accepted on June 13, 1986 when Ridomil/Bravo 81W was registered. Please refer to Residue Chemistry Review Dated November 26, 1985 and subsequent CIBA-GEIGY response dated January 7, 1986 for discussion. Because these rates have already been reviewed and accepted by the Agency and are not considered to be part of the proposed amendments submitted with the label under discussion, the conclusions drawn by the Agency are questionable.

RCB's Response:

Registered use of chlorthalonil on tomatoes are summarized in the Chlorothalonil Registration Standard, as follows:

"The 75% WP, 12.5% FlC, and 4.17 lbs./gal FlC formulations are registered for foliar application on field-grown tomatoes at 1.13 to 2.5 lbs. ai/A, ca 1.42 lbs. ai/A, and 1.13 to 2.5 lbs ai/A, respectively. Applications are made at 7 to 10 day intervals beginning 5-6 weeks before harvest. Application may be made using ground or aerial equipment. No PHI is in effect.

The Ridomil/Bravo 81W label calls for application of 1 1/2 to 3 lbs. (up to 2.16 lbs. ai/A) of product to tomatoes at 14 day intervals. No PHI is in effect. To minimize the potential for resistance, do not make more than 4 applications of Ridomil/Bravo 81W per crop.

Chlorothalonil residue data in or on tomatoes were submitted to the Agency in connection with PP#7F0599, PP#9F1024, and PP#0F2405. Based on a review of these data (conducted in connection with the Chlorothalonil Registration Standard) the Agency concluded that the available residue data do not support the established tolerance for combined residues of chlorothalonil and its metabolites in or on tomatoes.

Residue data submitted in response to the Chlorthalonil Registration Standard Data Call-In, indicate that the established tolerance for tomatoes at 5.0 ppm will not be exceeded as a result of this proposed amendment. Tomatoes from field trials in FL were treated 9 to 16 times with chlorothalonil at 2.08 lbs. ai/A and harvested on the last day of treatment.

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Chlorothalonil/metabolite residues ranged from 0.06 to 4.6 ppm. The maximum residue value found (4.6 ppm), reflects treatment at approximately 2x that proposed in the label amendment.

We conclude that deficiency 5a is resolved.

cc:R.F.,S.F.,Circu,Reviewer, Amended Reg. File, PMSD/ISB
RDI:EZ:11/16/87:RDS:11/16/87
TS-769:RCB:FBS:fbs:557-1883:CM#2:RM#814:11/17/87