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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

SEP 29 1994

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SECTION 18 EXEMPTION FOR USE OF CHLOROTHALONIL ON COLLARD GREENS, MUSTARD GREENS and TURNIPS.

To: Susan Stanton, PM Team 41 (7505C)
From: William D. Wassell, CBTS (7509C)

*William D. Wassell 9/29/94
Robert J. Wick*

ID#: 94GA0008
DP Barcode: D207428
CBTS#: 14355
Chemical

EPA Approved Common Name: Chlorothalonil
Chemical Name: Tetrachloroisophthalonitrile
Formulation Trade Name: Bravo® 720
Registration#: 50534-188
Class: Fungicide

State or Agency applying for exemption: Georgia
Type of exemption: emergency

Reason: To control a complex of fungal diseases (downy mildew and various varieties of leafspot) on approximately 2,300 acres of "leafy greens" grown for processing in the Georgia counties of Macon, Colquitt and Peach.

RECOMMENDATION

TOX considerations permitting and provided the proposed labeling is modified to include a restriction for a maximum of 4 applications per growing season, CBTS has no objection to the issuance of this Section 18 exemption. An agreement should be made with FDA regarding the legal status of the treated collard greens, mustard greens and turnips (root and greens) in interstate commerce.

CONCLUSIONS

1. For the purpose of this Section 18 request only, the metabolism of chlorothalonil in/on "leafy greens" is adequately understood. The residues of concern are parent and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile. Also, EPA has expressed concern over residues of hexachlorobenzene (HCB), an impurity formed in the manufacturing process.
2. CBTS concludes the proposed use directions for chlorothalonil are not adequate and must be modified to include a restriction for a maximum of 4 applications per growing season.
3. The nature of the residue in animals is not of concern, as no feed items are involved in this request.
4. Adequate methods are available for the enforcement of the current tolerance expression. Method I in PAM II determines residues of chlorothalonil and its 4-hydroxy metabolite and may be utilized for enforcement purposes. Additionally, CBTS has recommended for a method

entitled "General Analytical Procedure for the Determination of Residues of Chlorothalonil (SDS-2787), SDS-3701, SDS-46851, HCB and PCBN on Selected Crops" to be published in PAM II (see our memo 2/22/91, W.T. Chin, Ph.D.). This method has not yet appeared in PAM II.

5. Analytical reference standards for chlorothalonil and hexachlorobenzene are available from Ultra Scientific, North Kingstown, RI (401-294-9400). A reference standard of the 4-hydroxy metabolite of chlorothalonil is available from the Agency's Pesticides and Industrial Chemical Repository, RTP, NC.

6. CBTS concludes that maximum residues of chlorothalonil and its 4-hydroxy metabolite are not likely to exceed 25 ppm in mustard greens, collards and turnip greens or exceed 1.0 ppm in turnip roots as a result of the proposed use. HCB residues are not likely to exceed 0.12 ppm in mustard greens, collards and turnip greens or exceed 0.005 ppm in turnip roots. There are no residue data available for turnip roots; the residue estimates for this commodity are based on residue data for chlorothalonil only on carrots. There are no data for the 4-hydroxy metabolite of chlorothalonil and HCB in/on carrots in our files.

7. Anticipated residue estimates based upon chlorothalonil data for turnip greens, collards, kale and spinach have been calculated for this use and we conclude that for dietary exposure estimates residues of chlorothalonil per se should average approximately 3.60 ppm in/on turnip greens, collards and mustard greens as a result of the proposed use. Anticipated residue estimates have not been calculated for chlorothalonil in/on turnip roots and HCB in/on any of the subject commodities, because there are no chlorothalonil residue data on turnip roots and only two HCB data points on greens (none on roots).

8. The residue data used in the evaluation of this Section 18 request were generated by IR-4 (see PP#6E1841, MRID Nos. 00161165 and 00161190). Additional residue data submitted with this Section 18 request were generated by ISK Biotech Corporation with Ricerca, Inc. conducting the analytical portion of the study (no MRID No., ISK Document Number 5803-93-0210-CR-001). Residue data from carrots (MRID Nos. 115051 and 116868) were translated to turnip roots and these data were generated by Diamond Shamrock Corporation.

9. CBTS concludes the State of Georgia has not satisfied the residue data requirements outlined in our letter of 10/18/93 (Douglas D. Camp to Georgia Department of Agriculture). For additional information see the "Other Considerations: Progress Toward Registration" section of this review.

A Comparison of Proposed Label and the Residue Data Parameters Used in CBTS's Decision

	<u>Proposed Use</u>	<u>Residue Data</u>
chemical	chlorothalonil	chlorothalonil
formulation	Bravo 720	Bravo 6F, Bravo 720
crop	collard greens, mustard greens and turnips	collard greens, mustard greens, turnip greens, kale, escarole, carrots
method of application	ground equipment	ground
# of applications	no limit	3 to 5 (greens) and 12 (carrots)
timing	7 to 10 day intervals 14 day PHI	7 to 10 day intervals 7 and 14 day PHI (greens) 13 day PHI (carrots)

Rate/application	0.75 to 1.125 lbs ai/A	1.125 to 1.5 lbs ai/A
Rate/year or season	4.5 lbs ai/A/season	3.4 to 6.0 lbs ai/A/season
maximum residue	N/A	25 ppm (greens); 1 ppm (carrots)
restrictions		Applications are permitted from the time of approval through 6/30/95. Up to 2,300 acres may be treated.

Residue data taken from: PP#6E1841, MRID Nos. 00161190 and 00161165 (for the greens). CB (formerly RCB) concluded that a tolerance level of 25 ppm was appropriate for the greens (see our memo of 10/13/76, W.S. Cox). Additional residue data for chlorothalonil in/on mustard and collard greens was included in the current submission residue data from carrots (MRID Nos 115051 and 116868) was translated to turnip roots.

Additional Information:

CBTS notes that the State of Georgia has requested this Section 18 exemption for "leafy greens (mustards, turnips, and collards) for processing/frozen pack only", a crop grouping we do not recognize. Mustard and collard greens are members of the proposed crop subgroup Leafy Brassica greens. Currently, collard greens and mustard greens are members of the Brassica leafy vegetables crop group and turnip greens is a member of the leaves of roots and tubers group. CBTS will refer to the individual commodities in our discussions. CBTS will not recommend for a use on leafy greens grown specifically for the processing market, because we believe this restriction to be impractical for a Section 3 registration.

The State of Georgia has requested this Section 18 exemption at least once prior to the current request. In conjunction with the previous request, CBTS reviewed magnitude of residue data from PP#6E1841 (MRID Nos. 00161165 and 00161190) for chlorothalonil per se in/on turnip greens, collards, kale and spinach. Upon review of this data, we concluded the maximum residue level of chlorothalonil and its 4-hydroxy metabolite should not exceed 25 ppm in or on collards, mustard greens and turnip tops (see our memo of 3/11/93, M.I. Rodriguez and R. Lascola). CBTS has estimated HCB residues as 0.5% of chlorothalonil residues (i.e 0.005 x 25 ppm or 0.12 ppm in or on collards, mustard greens and turnip tops, see our memos of 4/11/89 and 8/23/88, D. Edwards). Also based upon this data, we calculated average residue levels in unwashed "leafy greens" of 8.5 ppm for chlorothalonil per se and estimated a 50% reduction in residues upon washing of the greens or 4.25 ppm of chlorothalonil per se. We concluded the 4.25 ppm value should be utilized for dietary exposure calculations for collards, mustard greens and turnip tops (see our memo of 3/31/93, D. Edwards).

In conjunction with this request, the State of Georgia has submitted residue data for chlorothalonil, its 4-hydroxy metabolite and HCB in/on collards and mustard greens from two field trials. In these studies, plots of collards and mustard greens were treated with 5 or 3 applications, respectively, of Bravo 720 at a rate of 1.125 lbs ai/A. The applications were made at approximately 7 day intervals and untreated and treated samples were collected 13 and 14 days after the final application. The raw agricultural commodities were analyzed and processed according to normal agricultural practices. The average chlorothalonil levels found on mustard and collard greens (RACs) were 2.5 and 1.51 ppm, respectively. Chlorothalonil residues decreased to 0.26 ppm and 0.19 ppm for mustard and collard greens, respectively, after washing, blanching and freezing/packing. Residue levels of the 4-hydroxy metabolite of chlorothalonil were generally at or below 0.01 ppm throughout the study. The average HCB residue levels in/on mustard and collard greens were 0.00094 ppm and 0.00068 ppm, respectively. HCB residue levels were below the

quantification limit for the method (<0.0005 ppm) after processing. Fortification recovery data for chlorothalonil, its 4-hydroxy metabolite and HCB from collards and mustard greens were included with the residue data, but the analytical method utilized to generate the residue data was not included.

In conjunction with this request, we are revising our calculated average residue levels to include the residue data for chlorothalonil *per se* in/on mustard and turnip greens that has been submitted with the proposed exemption. We have now calculated average residues levels in unwashed "leafy greens" of 7.20 ppm of chlorothalonil *per se* and estimated a 50% reduction in residues upon washing of the greens or 3.60 ppm of chlorothalonil *per se*. A residue level of 3.60 ppm of chlorothalonil *per se* should be utilized for dietary exposure calculations for collards, mustard greens and turnip tops.

Magnitude of residue data for chlorothalonil in/on turnip roots are not available. CBTS will translate residue data from carrots to turnip roots for the purpose of this Section 18 request. A tolerance for chlorothalonil and its 4-hydroxy metabolite is established in/on carrots at a level of 1.0 ppm as a result of treatment to the growing crop at a rate of 1.13 to 1.5 lbs ai/A with no minimum preharvest interval or maximum seasonal use rate. Residue data for carrots were submitted in conjunction with PP#7F0599 and PP#1F1024 (MRID Nos. 114051 and 116868). This data was summarized in the Residue Chemistry Chapter of the Registration Standard for chlorothalonil dated 9/15/83. In these three field trials, carrots were treated 12 times at a rate of 1.12 lbs ai/A and harvested 13 days following the final application. For carrots with their crowns removed, residues of chlorothalonil *per se* were less than 0.67 ppm. CBTS concludes residue levels of chlorothalonil and its 4-hydroxy metabolite should be less than 1.0 ppm in or on turnip roots as a result of this Section 18 request. CBTS estimates HCB residues should be no greater than 0.005 ppm (i.e. 0.005 x 1.0 ppm) in or on turnip roots as a result of the proposed use.

The State of Georgia has submitted monitoring data for various pesticides in or on collards, green beans, turnip greens, and squash. The data outlines the results of the analysis of 13 samples by multi-residue methods. We note that residues of chlorothalonil, its 4-hydroxy metabolite and HCB were not detected in any of the samples. The Georgia Department of Agriculture has also submitted a summary of monitoring data for residues of chlorothalonil. The summary indicates the total number of samples analyzed, the number of samples in which chlorothalonil residues were detected and the number of "violative" samples. The summaries do not define the meaning of "violative" samples, but indicates that out of 137 samples analyzed 2 samples were characterized as "violative". This data does not alter our conclusions concerning estimated residue levels in "leafy greens" as a result of applications of chlorothalonil.

Other Considerations: Progress Toward Registration

The Agency has granted exemptions to GA for this use since the spring of 1993. The use of chlorothalonil on leafy greens is being requested as a replacement for the EBDCs. The use of the EBDCs on leafy greens was canceled as part of the Agency's Special Review of the EBDC fungicides. In conjunction with the previous Section 18 requests for this use the Agency has determined that the risk from the long-term use of chlorothalonil on leafy greens may be comparable to the risk from the use of the EBDCs on leafy greens. Therefore, in granting last years exemption, the Agency has stated that certain residue data requirements must be met by the State of Georgia prior to the granting of another exemption request. The residue data requirements were outlined in a letter (dated: 10/18/93) from Douglas D. Camp to the Georgia Department of Agriculture. The residue data requirements will not be restated in this review, but will be referred to as Items 1 through 5 from pages 3 through 5 of the 10/18/93 letter. RD has requested CBTS to determine if these residue data requirements have been fulfilled in the current exemption request.

Item 1: The data requirements under this item (3 field trials on mustard greens) have not been fulfilled. The current submission includes the results of two field trials in which plots of collards and mustard greens were treated with 5 or 3 applications, respectively, of Bravo 720 at a rate of 1.125 lbs ai/A. At this time we are unable to conclude if the submitted field trials are adequate for a Section 3 registration, because a formal petition for the use has not been submitted and we have not been informed of the proposed use pattern. The Agency had not requested fields trials on collards.

Item 2: The data requirements under this item (2 field trials on turnips) have not been fulfilled. Field trials utilizing turnips have not been submitted in conjunction with this request.

Item 3: The requirements under this item have not been fulfilled. ISK Biotech indicates the submitted studies were conducted in compliance with the Good Laboratory Practice Standards under 40 CFR Part 160, but because a petition for this use has not been submitted we can not determine if the studies reflect the proposed use of the product on leafy greens.

Item 4: The requirements under this item have not been fulfilled. Fortification recovery data for chlorothalonil, its 4-hydroxy metabolite and HCB from collards and mustard greens were included with the residue data, but the analytical method utilized to generate the residue data was not included. Therefore, CBTS is unable to conclude that the method is adequate and we cannot determine if additional method data such as a PR 88-5 validation or validation of the method by the Agency is needed.

Item 5: The requirements under this item have not been fulfilled. The exemption request states that ISK Biotech will be seeking Section 3 registration for the use of chlorothalonil on leafy greens intended for the processing/frozen pack market. ISK Biotech should be informed that CBTS will not recommend for a use on leafy greens grown specifically for the processing market, because we believe this restriction to be impractical for a Section 3 registration. ISK Biotech has submitted the results of a study in which fresh greens were processed to frozen pack greens, but a study in which the effects of consumer washing and cooking on residue levels has not been submitted.

CBTS concludes the State of Georgia has not satisfied the residue data requirements outlined in our letter of 10/18/93 (Douglas D. Camp to Georgia Department of Agriculture).

cc: RF, circ., Chlorothalonil Section 18 file, W.D. Wassell, R. Griffin (CCB).
RDI: RSQuick: 09/28/94; MFlood: 09/29/94; RALoranger: 09/29/94.
7509C:CBTS:WDWassell:wdw:CM#2:Rm 804U:305-6135:09/19/94.
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