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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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 (H7505C)
From: William D. Wassell, CBTS (H7509C) 9/7/93

ID#: 93GA0008
DP Barcode: D194382
CBTS#: 12406
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: specific

Reason: To control a complex of fungal diseases (downy mildew and various varieties of leafspot) on approximately 25,000 acres of "leafy greens" throughout the State of Georgia.

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.

CBTS/HED recommends that this memo be forwarded to the applicant in its entirety.

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 anticipates that 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 data for carrots.

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* will average approximately 4.25 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.

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). Residue data from carrots (MRID Nos. 115051 and 116868) was translated to turnip roots and these data were generated by Diamond Shamrock Corporation.

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

	Proposed Use	Residue Data
chemical	chlorothalonil	chlorothalonil
formulation	Bravo 720	Bravo 6F

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 day PHI (greens) 13 day PHI (carrots)
rate/application	0.75 to 1.125 lbs ai/A	1.5 lbs ai/A
rate/year or season	4.5 lbs ai/A/season	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 6/30/94. Up to 25,000 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). 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", a crop grouping we do not recognize. 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.

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. Rodriquez 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).

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 chlorothalonil and its 4-hydroxy metabolite in or on turnip greens, mustard greens and collards. The Georgia Department of Agriculture indicates they collected these samples (9 samples in all) from a farm in which Bravo 720 was applied to the growing crops at the recommended rate and collected after the required preharvest interval. Samples were analyzed according to the PAM II method for the determination of chlorothalonil and its 4-hydroxy metabolite. Fortification recovery data were not reported. Chlorothalonil residue levels ranged from nondetectable (<0.01 ppm) to 3.86 ppm and levels of the 4-hydroxy metabolite of chlorothalonil ranged from nondetectable (<0.01 ppm) to 0.35 ppm. A sample of collards contained the highest residue level which was 3.86 ppm of chlorothalonil and 0.04 ppm of the 4-hydroxy metabolite. These data indicate that residues should be below the recommended action level of 25 ppm and can be in the range of our estimated average residue level of 4.25 ppm. These data do not change any of our previous conclusions.

CBTS has been requested by RD to outline the data requirements for both a national registration and a regional registration for the raw agricultural commodities collards, mustard greens and turnips. **Please Note:** The registration requirements are contingent upon the chlorothalonil reregistration requirements (i.e. metabolism, analytical methods, storage stability, rotational crop and product chemistry) being fulfilled. Currently, residue data for chlorothalonil and its 4-hydroxy metabolite are required for tolerance setting purposes. Residue data for hexachlorobenzene (a formulation impurity) are not currently required for all uses of the fungicide, but we strongly suggest that residue data are generated for HCB as it most likely will be necessary to calculate anticipated residue levels for HCB from the proposed use. The analytical method utilized for generation of HCB should have quantification limit at approximately 0.003 ppm or less. For a national registration, magnitude of residue studies conducted at the maximum seasonal use rate and at the minimum preharvest interval for the commodities would be required as outlined in Table 1.

Table 1. Magnitude of Residue Data Requirements for National Registrations of Collards, Mustard Greens and Turnips.

Commodity	Region	Number of Trials per Region
Collards	VA/NC/SC/GA/AL/TN	2
	FL	1
	OK/TX	1
	CA	1
Mustard Greens	VA/NC/SC/GA/AL/TN	1 (2)[1]
	LA/MS/AR	1 (2)
	MI/MN/OH/IN/KY/IL/MO/IA/ND/SD/NE/KS	1 (1)
	OK/TX	1 (2)
	CA	1 (1)
Turnips[2]	VA/NC/SC/GA/AL/TN	1
	FL	1
	MI/MN/OH/IN/KY/IL/MO/IA/ND/SD/NE/KS	1
	OK/TX	1
	CA	1

[1] Numbers of trials in parentheses are applicable to a crop subgroup registration for the Leafy Brassica Greens crop subgroup (see discussion below).

[2] Residue data for turnip tops and roots are required.

Please Note: A proposed rule for the revision of crop groups has recently been published in the Federal Register. In this proposed rule, EPA has proposed the creation of a crop subgroup that includes among other commodities mustard greens and collards. This subgroup would be called the "Leafy Brassica Greens Subgroup" and the representative commodity of this subgroup would be mustard greens. If this rule is promulgated, then magnitude of residue data would be required for mustard greens only in order to obtain a registration for the commodities of the crop subgroup.

For a regional registration of chlorothalonil for GA only on collards, mustard greens and turnips, magnitude of residue study requirements are as follows: (i) three field trials at the maximum seasonal use rate for each individual commodity or (ii) two trials for each individual commodity with each field trial consisting of 4 subplots and of these subplots two should be treated at the maximum seasonal application rate and two should be treated at an exaggerated rate of 2x the maximum seasonal use rate for each individual commodity. In each of the above scenarios the minimum preharvest interval should be utilized and two composite samples per plot should be collected (i.e. for option (i) a total of six treated samples per commodity and for option (ii) a total of eight treated samples per commodity). For all magnitude of residue studies, unwashed commodities should be analyzed, but for chlorothalonil anticipated residue data is usually required for all

commodities. Therefore, residue reduction studies may be required.

We strongly urge that if these registrations are sought then protocols for the magnitude of residue studies and residue reduction studies should be submitted to the Agency for review prior to initiation of the studies.

RDI: R.S. Quick: 9/2/93; R. Loranger: 9/2/93; D. Edwards: 9/3/93

cc: RF, circ., Chlorothalonil Section 18 file, W.D, Wassell, R. Griffin