SECTION 18 EXEMPTION FOR USE OF CHLOROTHALONIL ON COLLARD GREENS, KALE, MUSTARD GREENS, AND TURNIPS

To: Susan Stanton, PM Team 41 (H7505C)  
From: Maria I. Rodriguez and Robert Lascola, CBTS (H7509C)

ID#: 93GA0006  
DP Barcode: D188229  
CBTS#: 11393  

Chemical  
EPA Approved Common Name: Chlorothalonil  
Chemical Name: 2,4,5,6-tetrachloroisophthalonitrile  
Formulation Trade Name: Bravo 720, Terranil 6L  
Registration#: 50534-188, 9779-320  
Class: Fungicide  

State or Agency applying for exemption: GA  
Type of exemption: Specific

Reason: To control a complex of fungal diseases (incl. downy mildew and other leafspot-causing diseases) causing damage throughout the entire state, concentrating in central and south Georgia (comprising ~14,500 of the 25,000 total acres statewide dedicated to "leafy greens").

RECOMMENDATION

TOX considerations permitting, 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 leafy greens in interstate commerce.

CONCLUSIONS

1. The metabolism of chlorothalonil in plants is adequately understood. The residues of concern are parent and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile. Also, EPA has expressed concern over hexachlorobenzene (HCB) and pentachlorobenzonitrile (PCBN), impurities formed in the manufacturing process.
2. The metabolism of chlorothalonil in/on animal commodities is not adequately understood. Satisfaction of this requirement will be carried out as part of the reregistration process. For the purposes of this Section 18 request, the nature of the residue in animals is not of concern.

3. Adequate methods are available for the enforcement of the current tolerance expression. Method I in PAM II, which is sensitive to residues of chlorothalonil and its 4-hydroxy metabolite, may be used for enforcement purposes. CBTS has recommended (W.T. Chin memo of 2/22/91) that a second method ("General Analytical Procedure for the Determination of Residues of Chlorothalonil, SDS-3701, SDS-46851, HCB, and PCBN on Selected Crops") also be published in PAM II.

4. Analytical reference standards for chlorothalonil are available from Ultra Scientific, N. Kingstown, RI (401-294-9400). The 4-hydroxy metabolite is available from the Pesticides and Industrial Chemicals Repository, RTP, NC.

5. CBTS anticipates that residues of chlorothalonil and its 4-hydroxy metabolite are not likely to exceed 25 ppm in mustard greens, collard greens, turnips, and kale as a result of the proposed use. HCB and PCBN residues are not likely to exceed 0.12 ppm and 0.3 ppm, respectively.

6. The residue data used in the evaluation of this Section 18 request were generated by IR-4 (see PP#6E1841). CB had no objections to the residue chemistry portions of that petition. However, no tolerances have been established, and to our knowledge that petition has been outstanding since 1978.

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

<table>
<thead>
<tr>
<th>chemical formulation</th>
<th>Proposed Use</th>
<th>Residue Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>chlorothalonil</td>
<td>chlorothalonil</td>
</tr>
<tr>
<td></td>
<td>Bravo 720 (liquid)</td>
<td>Bravo 6F</td>
</tr>
<tr>
<td></td>
<td>Terranil 6L (&quot;</td>
<td></td>
</tr>
<tr>
<td>crop</td>
<td>mustard, collard, turnip, kale</td>
<td>mustard, turnip, and collard greens, kale, escarole</td>
</tr>
<tr>
<td>method of application</td>
<td>ground equipment</td>
<td>ground (?)</td>
</tr>
<tr>
<td># of applications</td>
<td>4 maximum</td>
<td>3-5</td>
</tr>
<tr>
<td>timing</td>
<td>7-10 day intervals, 14 day PHI</td>
<td>7 day PHI</td>
</tr>
<tr>
<td>rate/application</td>
<td>1.125 lbs.ai./A.</td>
<td>1.5 lbs.ai./A.</td>
</tr>
<tr>
<td>rate/year or season</td>
<td>4.5 lbs.ai./A./season</td>
<td>6.0 lbs.ai./A./season</td>
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</tbody>
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maximum residue N/A 25 ppm* 
(chlorothalonil and 4-OH metab. only) 

geographical representation is adequate; up to 25,000 acres may be treated.

Residue data taken from: PP#6E1841, W.S. Cox memo of 10/13/76. Raw data from this study is not available. MRID#/Accession Number are not known. (*) The reviewer concluded that a tolerance of 25 ppm would be appropriate for the proposed use.

Additional Information

CBTS notes that the State of Georgia has requested this Section 18 exemption for "leafy greens", a category which we do not recognize. Collard and mustard greens and kale are members of the Brassica leafy vegetables group, and turnip greens is a member of the leaves of roots and tubers group. CBTS thus phrased its conclusions in terms of the individual commodities.

We have received some supplementary information from the State of Georgia. In a facsimile dated 3/4/93, 2 samples (one of mustard greens and one of collard greens) were treated with 2 applications each of Bravo 720 at 1.125 lbs ai/A. The spray interval for collards was 14 days, and for mustard was 8-9 days. Samples were collected at a 15-day (mustard) and 8-day (collards) PHI. The samples were not washed or treated in any way before analysis. The analytical method used was the "CFDA Organochloride Pesticide Residue Screen" (no description given). No residues were found in collards, and residues of 0.04 ppm were found in mustard. However, CBTS will not consider this data in this request for the following reasons. No GLP statement has been signed. No description or validation of the analytical method has been submitted. Only two data points were submitted.

Also, in the original Section 18 request, the State has submitted summaries of several other dietary exposure studies previously reviewed by the Agency, including studies on cabbage (MRID# 00158892) and celery (MRID# 00158893). CBTS is reluctant to use this information. Celery is not in the Brassica leafy vegetables crop group. Cabbage and broccoli, which are Brassica, have closed, compact structures, while the the crops under consideration have more open leaf structures, with a correspondingly larger surface area. One would expect that residues on the latter would be higher for a broadcast-type application, and thus residue data for broccoli and cabbage will not accurately predict residue data on mustard (and other) greens.

CBTS must base its estimate of chlorothalonil residue levels in mustard, collard, and turnip greens and kale on field residues, not on levels expected after processing for market. For the purposes of anticipated residue calculations, we note that these vegetables may be washed and cooked before consumption. No data on the effects of this preparation on "leafy
greens" is available. Residue data for cabbage indicates a 6-9-fold reduction in residues after washing and trimming (MRID# 00158892), but because of the physical differences between cabbage and "leafy greens", we cannot estimate the extent to which trimming and washing will reduce residues in "leafy greens".

No data depicting residues of HCB (a manufacturing impurity) in either "leafy green" or related commodities is available. CB has estimated HCB residues as 0.5% of chlorothalonil residues (D. Edwards, 4/11/89 and 8/23/88). Using this estimate, CB concludes that HCB residues will not exceed (0.005 x 25 ppm =) 0.12 ppm. Data from broccoli and cabbage residue trials (Chlorothalonil FRSTR, 2/19/88) indicated that PCBN residue levels were \leq 1.2% chlorothalonil residues. Using this estimate, CB concludes that PCBN residues are not likely to exceed 0.3 ppm. If, for TOX or dietary exposure concerns, more accurate residue estimates are needed for HCB and PCBN, additional residue data will have to be generated.

RDI: P.V.Errico: 3/10/93; R.Loranger: 3/10/93.
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