

PP#
PP#4E1502. Chlorothalonil on Green and Bulb
Onions. Amendment of October 21, 1974.

NOV 27 1974
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Coordination Branch
and Toxicology Branch, RD

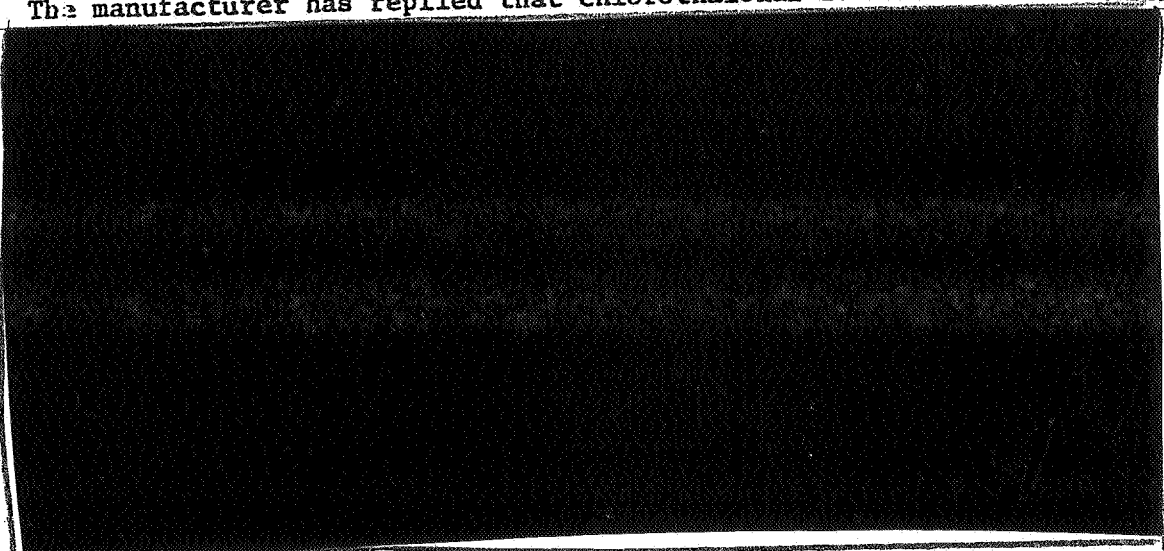
C.C. Compton on behalf of the IR-4 Committee and the manufacturer, Diamond Shamrock Chemical Company, have replied to our reject letter of August 13, 1974, (L.A. Zink, COB). The five deficiencies communicated in this letter are discussed below.

Deficiencies 1 and 3: The petitioner replies that the data submitted in Section D reflect combined residues of the parent and 4-hydroxy metabolite, thus resolving these deficiencies.

Deficiency 2: A revised Section B limiting use on green onions to a maximum of 3 applications and increasing the PHI to 14 days resolves this deficiency.

Deficiency 4: We required a description of the manufacturing process used for chlorothalonil and possibly residue data for hexachlorobenzene (HCB).

The manufacturer has replied that chlorothalonil is manufactured



MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

IMPURITY INFO NOT INCLUDED

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PRODUCT IMPURITY INFO NOT INCLUDED

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HCB analysis was conducted by GC using a flame ionization detector. The lower limit of detection is stated to be <0.02%.

Analysis of 308 batches of technical chlorothalonil showed no detectable HCB in 283 (92%) of the batches and an average of 0.05% HCB in the remaining 8% of the batches. The manufacturer states that as problems with the new facility are overcome, the HCB contamination is expected to decrease.

Although no residue data for HCB on onions following the application of Daconil containing 0.05% HCB is available, only trace residues of HCB are anticipated from this low level of contamination. This conclusion is supported by the following studies. No residues of HCB above background were found on alfalfa hay, asparagus or horseradish treated with Dacthal containing 0.3% HCB in the technical product. The application of PCNB containing 1.5% HCB resulted in maximum HCB residues in peanuts of 0.3 ppm. The treatment rates in terms of lbs. of HCB applied per acre were 0.03 and 0.15 lb. HCB/acre for the Dacthal and PCNB studies, respectively. This compares to only 0.0013 lbs. HCB/acre for three applications of chlorothalonil containing 0.05% HCB at the maximum rate of 2.25 lbs. chlorothalonil per acre. Because of the different use patterns and different crops studied, the Dacthal and PCNB results cannot be directly translated to onions. The Dacthal and PCNB treatments are generally preemergence treatments whereas Daconil can be applied up to 7 and 14 days before harvest for bulb and green onions, respectively. See the reviews of PP#3F1417 (F.D.R. Gee, 5/23/74) and PP#1F1083 (D.V. Reed, 2/23/72) for further details concerning HCB in Dacthal and PCNB, respectively. However, even if all of the HCB applied were to be present as a residue on onions, residues would be 0.05 ppm. Actually, residues, if present, would probably be much less than 0.01 ppm.

TB has indicated that the low level of HCB expected will not be of concern (Conversation with C.H. Williams, Ph.D. 11/20/74).

We conclude that this deficiency is resolved.

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Deficiency 5: Section B has been modified to limit use to ground application only, thus resolving this deficiency.

Recommendations

TB considerations permitting, we recommend that the proposed tolerances of 0.5 ppm on bulb onions and 5 ppm on green onions be established.

We note that EEEB has indicated that there are no problems with this use.

Richard D. Schmitt, Ph.D
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cc:

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RO-130(FDA)

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