

11/16/79

JA N Z

PP# 8F2107. Aldicarb in or on sorghum. Comments on Amendment of 9/11/79

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THRU: Chief, Residue Chemistry Branch (TS-769)

In our review of 2/22/79, the following deficiencies in the subject petition were given:

1) The proposed label contains the restriction, "Do not harvest within 90 days." There is a clear indication that from the proposed use (0.5-1.05 lb. a.i./acre) aldicarb residues could exceed the tolerance of 0.05 ppm on sorghum seed... We conclude that the petitioner should ask for a tolerance of 0.2 ppm for residues of aldicarb and its metabolites on sorghum grain.

2) Residue data on milling fractions by an adequately validated method are needed. Food additive tolerances should be proposed if needed.

3) The label should be clarified to limit use to grain sorghum.

The petitioner has forwarded a revised Section F that reflects a proposed tolerance of 0.2 ppm aldicarb and its metabolites in or on sorghum grain. Also, the petitioner has submitted a revised label that limits the application of the product to only grain sorghum. These actions satisfactorily resolved the above deficiencies Nos. 1 and 3 (Nos. 3a and 6 of our review 2/22/79 - J. Onley).

In response to deficiency No. 2 (No. 5 in our 2/22/79 review), the petitioner has asked us to waive the fractionation study or pursue the registration amendment on the basis of a conditional tolerance since the completion of residue analyses for a study that has already started is anticipated for late 1979 or early 1980. Samples were expected to have been available for fractionation early in September or October. Presumably, the fractionation study is nearly finished at this time.

Conditional tolerances are not set in the absence of the necessary residue data. Therefore, we still require the residue data for milled fractions. The above deficiency No. 2 still remains outstanding.

Recommendation

RCB continues to recommend against the establishment of the proposed tolerances until the above deficiency No. 2 has been resolved.

cc: Reviewer
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Reading file

EEE
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FDA

TS-769:RDI:Section Head: RQ:Date:11/16/79:J.G.Cummins:Data:11/16/79

RCB: Reviewer: J. H. Onley: LDT: X77324: CN#2: RM: 810: Date: 11/26/79