7/9/85

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 9 19[illegible]
JUL 9 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4E3049 [RCB #802]. Fenvalerate (Pydrin®) on Radishes. Re-evaluation of Proposed Tolerances Based on RCB's June 12, 1985 "Review of Pyrethroid Metabolism." (Date Received by HED on Reg. Division Data Review Record - 6/18/85).

FROM: Michael P. Firestone, Ph.D., Chemist M. P. Firestone
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: John H. Onley, Ph.D., Section Head John H. Onley
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Residue Chemistry Branch
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TO: Hoyt L. Jamerson, Minor Uses Officer
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

In RCB's previous review of the subject petition (see M. Firestone memo of 12/21/84), it was concluded that proposed tolerances of 8 ppm for radish tops and 0.3 ppm for radish roots would be adequate to cover residues of fenvalerate (parent compound only) resulting from the proposed use. However, depending on RCB's evaluation of pyrethroid metabolism, a root crop metabolism study with fenvalerate may be required and residues other than parent compound only may prove to be of concern.

RCB chemists K. Arne and R. Perfetti have now completed a study entitled "Regulatory Aspects of Pyrethroid Metabolism," which has been forwarded to TOX for formal comments (see C. Trichilo, RCB Branch Chief, memo of 6/12/85 to T. Faber, TOX Branch Chief, re: Review of Pyrethroid Metabolism).

Metabolism studies conducted with cotton, lettuce, apples, tomatoes, and soybeans demonstrated that the parent compound (fenvalerate) comprised from 72 to 96% of the terminal activity when the time from application to harvest ranged up to 85 days, assuring adequate time for metabolism. The only other significant residue found was a photodegradate (8 to 12% of the terminal activity) which TOX has previously determined to be not of toxicological concern (see A. Kocialski memo of 7/19/84). In RCB's recent review of a wheat metabolism study submitted in support of PP#4F3003/FAP#4H5419 and PP#4F3021 (see E. Haeberer memo of 5/3/85), it was concluded that the metabolism of fenvalerate in small grains is adequately understood and the residue of concern consists of parent compound only.

Although TOX has not yet had time to comment on RCB's comparative study of synthetic pyrethroids metabolism and reach any conclusions regarding the regulation of these pyrethroids, RCB will now reiterate its conclusion reached with regard to the nature of the residue in sugarbeets (see M. Firestone memo of 5/22/85) that at this time, the residue of concern in radishes (another root crop) is considered to consist of parent compound only. Upon completion of TOX's evaluation of RCB's study, the fenvalerate tolerance expression for plant commodities may or may not require revision in the future.

Other Considerations

An International Residue Limit Status sheet is attached to this review. Canada and Mexico have no tolerances/limits established to cover residues of fenvalerate in/on radishes. Codex has a temporary 0.05 ppm limit for residues in/on root and tuber vegetables. Since this limit is 6 times lower than the proposed U.S. tolerance reflecting actual residues in/on radish roots, these two tolerance/limits are not compatible.

RCB suggests that Codex consider the proposed U.S. tolerance of 0.3 ppm when establishing a permanent fluvalerate tolerance on radish roots.

Recommendation

At this time, RCB recommends for the proposed fluvalinate (parent compound only) tolerances of 0.3 ppm on radish roots and 8 ppm on radish tops, TOX and EAB considerations permitting.

Upon completion of TOX's evaluation of RCB's study of pyrethroid metabolism, the fenvalerate tolerance expression for plant commodities may or may not require revision in the future.

cc:R.F., Circu, Reviewer, TOX, EAB, EEB, PP#4E3049, PMSD/ISB
Robert Thompson (RTP), FDA
RDI:JHOnley:7/1/85:RDSchmitt:7/1/85
TS-769:RCB:CM#2:RM810:X7484:MPFirestone:wh:7/9/85

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: fenvalerate (Pydrin)

CCPR NO.: 119

PETITION NO.: 4E3049

REVIEWER: Michael P. Firestone

Codex Status

[ ] No Codex Proposal Step 6 or above

Residue (if Step 9):

Crop(s)	Limit (mg/kg)
[illegible]	0.05

Proposed U.S. Tolerances

Residue: fenvalerate

Crop(s)	Tol. (ppm)
radish tops	8.0
radish roots	0.3

CANADIAN LIMIT

Residue: fenvalerate

Crop(s)	Limit (ppm)
none [2]	

MEXICAN TOLERANCIA

Residue:

Crop(s)	Tolerancia (ppm)
none	

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Notes: Temporary pending full ADI. [illegible]

[2] There is a 0.1 ppm negligible [illegible]

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