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

AUG 30 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#5E3282 (RCB No. 1296) Pydrin® (fenvalerate) on Okra. Evaluation of Analytical Methods and Residue Data (Accession Number 073721).

FROM: Martin F. Kovacs, Jr., Ph.D., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: John H. Onley, Ph.D., Section Head
Tolerance Petition Section 2
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Hoyt L. Jamerson, Minor Uses Officer
Process Coordination Branch
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Interregional Research Project No. 4 Professor G.M. Markle, National Coordinator and National Director, Dr. R.H. Kupelian, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Stations of Arkansas, Florida, and North Carolina, request the establishment of a tolerance for the residues of the insecticide cyano (3-phenoxyphenyl) methyl-4-chloro-alpha-(1-methylethyl) benzeneacetate in or on the raw agricultural commodity (rac) okra at 0.1 ppm.

Pydrin tolerances are established for a variety of agricultural commodities ranging from 0.02 ppm on corn grain, peanuts and potatoes to 50 ppm on corn fodder and forage (see 40 CFR 180.379). Numerous rac tolerances (including food additive proposals) are pending at levels ranging from 0.01 ppm for popcorn kernels and cob to 100 ppm for bean vine hay.

Shell Oil Company has submitted a letter from E.L. Hobson, Ph.D., (Washington Representative, Regulatory Affairs - HS and E) to Hoyt L. Jamerson (Minor Uses Officer, Registration Division, EPA) authorizing the use of Shell Oil Company file nos. 201-401 (Pydrin® Insecticide 2.4 EC) and 201-402 (Technical Pydrin Insecticide) in support of the subject petition.

Conclusions

1. A revised Section B (label) restricting use to Florida only will be required unless the petitioner submits additional residue data for areas of use other than Florida (i.e., at a minimum NC and AR).Also,a revised Section F needs to be submitted requesting a tolerance with regional registration under Subsection (b) of 40 CFR 180.379 (see also discussion below under Conclusions 4a and 4c).

2. 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 can conclude, at this time, that the residue of concern in/on okra consists 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.

3. Adequate analytical methodology is available to enforce the proposed tolerance on okra.

4a. RCB recommends that the label (Section B) be revised to state "For use in Florida only" or alternatively, if use is intended elsewhere (i.e., as requested by the Agr. Expt. Stations in NC and AR) then additional okra residue data at the maximum proposed use rates and minimum PHI's will be needed from those States (see also Conclusion 1 above).

4b. RCB concludes that the proposed tolerance (0.1 ppm) will be adequate to cover fenvalerate residues on okra resulting from the proposed use if restricted to Florida only.

4c. The petitioner should repropose the tolerance as a tolerance with regional registration under a new Subsection (b) of 40 CFR 180.379. This residue conclusion cannot be extended to cover residues which may result from intended use in States other than Florida(see also Conclusion 1 above).

5. There are no feed items associated with okra. Therefore, no reasonable expectation of secondary residues on meat, milk, poultry or eggs will occur as a result of the proposed use.

6. An International Residue Limit Status sheet is attached. Since there are no Codex, Canadian or Mexican limits/tolerances established for fenvalerate (Pydrin) on okra, there are no compatibility problems.

Recommendation

We recommend that the proposed tolerance of 0.1 ppm for fenvalerate on okra not be established for the reasons given in Conclusions 1, 4a, and 4c above. Requirements for resolution of these deficiencies are also discussed in the appropriate Conclusions above.

The petitioner should be advised, that pending TOX Branch's opinion regarding the regulation of pyrethroids, the fenvalerate tolerance expression for plant commodities may require revision in the future as discussed in Conclusion 2 above.

Detailed Considerations

Manufacture and Formulation

The manufacturing process for fenvalerate was submitted with PP#0F2013 and reviewed in conjunction with that petition (memo of April 21, 1978, E.L. Gunderson).

Technical fenvalerate is formulated as Pydrin® Insecticide 2.4 Emulsible Concentrate (EPA Registration No. 201-401), which contains 2.4 lbs ai/gallon.

The inerts are all cleared under 40 CFR 180.1001 for use in pesticide formulations.

Proposed Use

For control of stinkbugs and corn earworm on okra, apply Pydrin® 2.4 EC via ground equipment only at a rate of 0.1 to 0.2 lb ai (5 1/3 to 10 2/3 fl oz) in 100 gal water per acre. Thirty to 140 gallons of finished spray solution/acre/application are to be used, the spray volume depending upon the size of the plants during the growing season. Repeat applications at 7-day intervals are permitted during the growing season, up to a maximum of 2.0 lbs ai/A/season, with the last application made no later than 1 day before harvest.

RCB's Comments/Conclusions re: Proposed Use

A revised Section B (label) restricting use to Florida only will be required unless the petitioner submits additional residue data for areas of use other than Florida(i.e.,at a minimum NC and AR). Further,a revised Section F needs to be submitted requesting a tolerance with regional registration under Subsection (b) of 40 CFR 180.379 (see also discussion below under Residue Data).

Nature of the Residue

No new plant metabolism studies were submitted in conjunction with this petition. Radiolabel metabolism studies have been carried out on cotton (PP#6G1755, see review of May 14, 1978, E.L. Gunderson), apple and lettuce (PP#8E2024, memo of June 21, 1978, E.L. Gunderson), tomatoes (PP#1F2367, memo of January 7, 1981, K. Arne), and soybeans (PP#0F2375, memo of December 23, 1980, K. Arne).

These studies indicate that Pydrin does not readily translocate and that degradation is slow. The predominant residue is the parent compound; however, a photodegradation product, 4-chloro-beta-(1-methylethyl)-alpha-(3-phenoxyphenyl) benzenepropane-nitrile, has been found at various residue levels in/on cotton-seed, tomatoes, lettuce, apples, pea vines, peas, almond hulls and celery.

TOX has concluded that residues of the photodegradate, from current uses, are not significant and that the photodegradate should not be included in the Pydrin tolerance expression (memo of July 19, 1984, Albin Kocialski).

RCB chemists K. Arne and R. Perfetti have 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 June 12, 1985, to T. Faber, TOX Branch Chief, re: Review of Pyrethroid Metabolism).

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 can conclude, at this time, that the residue of concern in/on okra consists 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.

Analytical Methodology

One method cited and used for enforcement purposes for residues of parent Pydrin compound is entitled "Determination of SD 43775 Residues in Crops, Animal Tissues, Soil and Water, Electron Capture Gas Chromatography Method, Shell Development Co., Bio Science Res. Center, California." This method, which is described in the Pesticide Analytical Manual Volume II (Pesticide Reg.Sec. 180.379) has undergone a successful method trial for Pydrin per se in cottonseed, meat and milk (see July 24, 1978, memo of J.H. Onley in conjunction with PP#7F2013).

The methodology employed by the petitioner to gather residue data on okra was entitled "Protocol for Fenvalerate Analysis in Okra."

In this procedure 25 g of finely chopped okra samples are blended with 200 ml hexane. The hexane extract is filtered through phase separating paper and anhydrous sodium sulfate. The filtrate is concentrated by a roto-evaporator to 5 ml at 35 °C, then diluted to 10 ml with hexane for electron capture gas-liquid chromatography. A Hewlett Packard GC, model 5840 equipped with a Ni^{63} electron capture detector and a glass column 160 cm x 2 mm ID packed with 3 percent OV-101 on 80/100 mesh Gas-Chrom Q was used. Operating temperatures were; oven 275 °C, injector 300 °C and detector 300 °C and the carrier gas was Argon 95 percent/Methane at 58 ml/min.

Submitted validation data using the latter method for okra fortified with Pydrin at levels of 0.1 and 0.5 ppm indicated recoveries of 94.0 and 75.2 percent, respectively. Control values were reported at < 0.02 ppm. Based on submitted chromatograms we estimate the limit of detection of the method to be ca 0.01 ppm and the sensitivity to be 0.02 ppm.

RCB concludes that adequate analytical methodology is available to enforce the proposed tolerance.

Residue Data

In the current petition treated and harvested okra samples were stored at 0 °F for 52 to 59 days prior to analysis. Previously submitted storage stability data at -10 °C for Pydrin on chopped collards (see M.F. Kovacs, Jr. memo of March 19, 1984, re: PP#4E2974) indicated an average recovery of 79 percent for Pydrin following storage for up to 8 1/2 months. Currently submitted

storage fortification studies for okra samples stored for 36 days at 0 °F indicated maximum degradation of 8 percent for residues of Pydrin. Because of the demonstrated storage stability of Pydrin on various rac's coupled with the relatively short storage interval of Pydrin treated okra samples in the current petition, we are raising no questions with regard to the stability of Pydrin in the okra samples analyzed.

Residue studies (1984) for okra were conducted at one location in Florida only. At this location, Pydrin® 2.4 EC was applied with ground spraying equipment to okra at 0.2 and 0.4 lb ai/100 gal water (1x) and (2x), respectively, with finished spray volumes applied at 30 gal for the first treatment increasing to 140 gal/acre/treatment for each of the last 4 treatments. A total of nine applications at 7-day intervals were made which represented a total of 1.86 and 3.72 lbs ai/A/season or 0.93x and 1.86x the maximum total ai/A permitted per growing season. Okra samples were collected 1, 3, and 5 days following the last application at each treatment rate.

Following a 1x application rate (0.93x the maximum permitted per growing season) uncorrected residues of Pydrin on okra were reported as (<0.02 to 0.04), (< 0.02 to 0.03) and <0.02 ppm at PHI's of 1, 3, and 5 days, respectively. Following a 2x application rate (1.86x the maximum permitted per growing season) comparable residue values reported on okra were (0.03 to 0.07), (0.04 to 0.06) and (0.02 to 0.04 ppm).

RCB's Comments/Conclusions re: Residue Data

1. The residue data on okra submitted in this petition are extremely limited in that they reflect only one location in one State (Florida). According to both Fruit and Vegetable Facts and Pointers (Okra) February 1975 and Vegetable Growing Handbook 2nd Ed. W.E. Splittstoesser (AVI Publ. Co. Inc.) 1984, okra is a warm season plant similar to cucumber and tomato and can be grown anywhere in the U.S. (lower 48 States) where most other vegetables are grown except in the coolest northernmost parts or at high altitudes. According to 1964 data on okra acreage harvested (which reflects the latest official production figures according to Foods and Food Production Encyclopedia D.M.Considine and G.D.Considine; Van Nostrand Rheinhold Inc. (1982)) the leading States in order of acreage harvested were GA, TX, TN, FL, AL, LA, and AR; FL accounted for 12 percent and the additional (6) States listed, 75 percent of total US acreage.

Accordingly, RCB recommends that the label (Section B) be revised to state "For use in Florida only" or alternatively, if use is intended elsewhere (i.e., as requested by the Agr. Expt. Stations in NC and AR) then additional okra residue data at the maximum proposed use rates and minimum PHI's will be needed from those States.

RCB also recommends that the petitioner submit a revised Section F requesting a tolerance with regional registration under Subsection (b) of 40 CFR 180.379.

2. RCB concludes that the proposed tolerance (0.1 ppm) will be adequate to cover residues in okra resulting from the proposed use if restricted to Florida only.The petitioner should repropose the tolerance as a tolerance with regional registration under Subsection(b)of 40 CFR 180.379. This residue conclusion cannot be extended to cover residues which may result from intended use in States other than Florida.

Residues in Meat, Milk, Poultry and Eggs

There are no feed items associated with okra. Therefore, no reasonable expectation of secondary residues in meat, milk, poultry or eggs will occur as a result of the proposed use.

Other Considerations

An International Residue Limit Status sheet is attached. Since there are no Codex, Canadian or Mexican limits/tolerances established for fenvalerate (Pydrin) on okra, there are no compatibility problems.

Attachment: (International Residue Limit Status sheet)

cc:R.F.,Circu,Reviewer,EAB,EEB,FDA,PP#5E3282,PMSD/ISB
RDI:Section Head:J.H.Onley:Date:8/20/85:RDSchmitt:Date:8/20/85
TS-769:RCB:CM#2:RM814:X7484:Typist Kendrick:edited:MFKovacs
Edited by Wh:8/29/35

I Am 5/13/95

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL [illegible] PETITION NO. [illegible]

CCPR NO. 119 Reviewer: [illegible]

Codex Status

[ ] No Codex Proposal
Step 6 or above

Proposed U.S. Tolerances

[illegible]

Residue (if Step 9): [illegible]

Residue: [illegible]

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

Crop(s)	Tol. (ppm)
[illegible]	[illegible]

CANADIAN LIMIT

Residue: [illegible]

Crop	Limit (ppm)
[illegible]	

MEXICAN TOLERANCIA

Residue: [illegible]

Crop	Tolerancia (ppm
[illegible]	

NOTES:

Page [illegible] of [illegible]