RF

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

SEP 29 1988

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: PP#8E3636. Fenvalerate on Pineapples. Evaluation of Analytical Methods and Residue Data. (DEB No. 3876, MRID Nos. 406004-00, 406004-01).

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Health Effects Division (TS-769C)

To: Hoyt L. Jamerson, PM Team 43
Emergency Response and Minor Use Section
Registration Division (TS-767C)
and
Toxicology Branch - Insecticide/Rodenticide
Health Effects Division (TS-769C)

Thru: Robert S. Quick, Head
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (TS-769C)

The petitioner, IR-4, on behalf of the IR-4 National Director, Dr. R. H. Kupelian, and the Agricultural Experimental Station of Puerto Rico, requests the establishment of a tolerance for the residues of the insecticide cyano (3-phenoxyphenyl) methyl-4-chloro-alpha-(methylethyl) benzeneacetate (aka pydrin, fenvalerate,esfenvalerate) in/on the r.a.c. pineapple at 0.50 ppm. Tolerance with regional registration for use in Puerto Rico only is requested.

Conclusions

1. The nature of the residue in plants and animals is understood. The residue of concern is fenvalerate.

2. Adequate analytical methodology is available for enforcement of the proposed tolerance (PAM II).

3. The petitioner will have to submit residue data on pineapple forage from the maximum proposed use. A pesticide tolerance for pineapple forage will be needed. Alternatively

the petitioner may submit a revised Section B stipulating a feeding restriction for pineapple forage.

4. Since pineapple is not a minor crop, the proposed use must meet the 5 criteria listed in the federal register notice on minor uses (Vol. 51, No. 63, pp 11341-11346) to be considered for regional registration. This submission does not satisfy these criteria. (See discussion under Residue Data.)

5a.The residue data are insufficient in number and geographic distribution. Additional residue data are needed on the whole fruit, dried bran, juice and forage reflecting the maximum proposed use pattern from representative pineapple growing areas including Hawaii.

5b.Even if the petitioner can satisfy us that the proposed use meets the 5 criteria in the 1986 FR Notice, the available residue data from Puerto Rico are an inadequate basis upon which to establish a tolerance with regional registration. Residue data from Puerto Rican sites reflecting the maximum proposed use are needed for whole pineapple, dried bran, juice and forage.

5c.No conclusions can be drawn concerning the adequacy of the proposed tolerance until the above data are submitted.

6. No conclusions can be drawn concerning possible secondary residues in meat, milk, poultry and eggs until additional residue data are submitted for bran and forage (if a feeding restriction is not proposed) reflecting the maximum proposed use pattern.

7. The International Residue Limit Status sheet is attached. There are no established tolerances for fenvalerate (pydrin) in/on pineapples in Canada, Mexico or by Codex, therefore there are no conflicts.

Recommendation

RCB recommends against establishment of the proposed 0.50 ppm tolerance for fenvalerate in/on pineapples for the reasons cited in Conclusions 3, 4, 5a, 5b, 5c and 6.

Detailed Considerations

Manufacturing Process

The manufacturing process is discussed in detail in the Confidential Appendix attached to the new formulation registration review of November 26, 1984 (201-URI. New Pydrin Formulation - SS Pydrin 1.9 EC. Accession Nos. 254112, 254117, 254119, Leung Cheng).

Formulation

Asana Insecticide 1.9 Emulsible Concentrate is an emulsible concentrate containing 24% active ingredient (S)-cyano (3-phenoxyphenyl) methyl-(S)-4-chloro-alpha-(1-methylethyl) benzeneacetate [1.9 lbs fenvalerate (at least 75% insecticidally active isomer SD 47443, SS Pydrin) per gallon] and 76% inert ingredients. All of the inerts have been cleared under 40 CFR 180.1001.

Proposed Use (MRID #406004-00)

For the control of gummosis in pineapples apply spray by ground equipment at the rate of 0.025 to 0.050 lbs active ingredient per acre in 100 gallons of water. Make first application at pineapple flowering and repeat as needed at 7-10 day intervals for a maximum of 4 applications between pineapple flowering and two months before harvest. The use is limited to Puerto Rico.

Nature of the Residue in Plants

The nature of the residue in plants is adequately defined. The residue of concern is the parent compound, fenvalerate. Detailed discussion of plant metabolism studies on cotton, apples, lettuce and tomatoes are included in the reviews of PP#'s 3F3002, 4F3003, 4F3004, and 2F2657.

Nature of the Residue in Animals

Pineapple forage and pineapple bran are animal feed items. The petitioner proposes neither a label restriction against the feeding of pineapple forage nor a forage tolerance.

Both poultry and cow metabolism studies have been discussed in previous reviews for fenvalerate.

Animal metabolism was discussed in detail in the new formulation registration review of November 26, 1984 (L. Cheng). Five metabolism studies on rats and one on rats and mice were conducted to compare the nature, qualitatively and quantitatively, of metabolism between the two technical materials containing different levels of active isomer SD 47443. ^{14}C-Fenvalerate labeled at the chlorophenyl and phenoxyphenyl position in racemic SD 43775 or SS isomer-enriched SD 92459 was

used. The racemic material contained 22% SS and 22% RR, while SD 92459 had 43% SS, 43% RR.

Of the administered dose 69-112% was eliminated in urine and feces after 5-6 days. Significant residues were found in fat but not in kidney, liver or muscle. There was no significant difference between racemic and SS isomer-enriched fenvalerate with regard to kinds and amounts of metabolites.

The metabolism included hydroxylation of the phenoxy ring, ester cleavage of the parent, and hydroxylation of chlorophenylisovaleric acid SD 44064 and phenoxybenzoic acid SD 44607.

The nature of the residue in animals is adequately defined. The residue of concern is the parent compound, fenvalerate.

Analytical Methodology

The analytical method used to gather data for this petition is entitled "Determination of SD 43775 Residue in Crops, Animal Tissues, Soil and Water, Electron Capture Gas Chromatographic Method," MMS-R-478-1. A successful petition method validation (PMV) was conducted on cottonseed in conjunction with PP#7F2013 (memo of July 24, 1978, J. H. Onley). The method is published in the PAM, Volume II. The minimum detectable level of fenvalerate is 0.02 ppm in crown and 0.01 ppm in bran and pulp.

Validation data for pineapple crown fortified at 0.02, 0.10 and 0.50 ppm reflected recoveries ranging from 80 to 100%. Bran fortified at 0.01, 0.10 and 0.50 ppm yielded recoveries of 90 to 110%. Pulp fortified at 0.01, 0.10 and 0.50 ppm yielded recoveries of 89 to 110%.

Confirmatory methodology (AFID-GC) is available, if needed.

We conclude that adequate analytical methodology is available to enforce the proposed tolerance for fenvalerate in/on pineapples.

Residue Data (MRID #406004-01)

Residue data were submitted from a single field trial conducted in Puerto Rico in 1986. Pineapple plants were treated four times with 0.02 and 0.05 lbs ai/acre and harvested 59 days after the last application.

Four fruits were harvested randomly from center rows and peeled to 2-3 lbs each. Residue analyses were performed on pineapple crown, bran and pulp. No residue data were provided from the lower application rate or the whole fruit. The maximum residues found from the 0.05 lbs ai/acre application were 0.08

ppm in crown, 0.02 ppm in bran, and <0.01 ppm in pulp. Storage stability studies indicated that residues in crown ranged from 48 to 64% after 10 months, 59 to 78% in bran and 93 to 114% in pulp after 3 months. If the residue values are corrected for losses in storage, maximum residues could be 0.16 ppm in crown, 0.03 ppm in bran and <0.01 ppm in pulp.

No data are provided for pineapple juice. The petitioner states that approximately 835 lbs of juice and 144 lbs of pineapple solids are produced from a ton of fruit, the remaining 45-50% are waste material not used for juicing. The petitioner concludes that even if 100% of the 0.08 ppm residue went into the juice, the proposed tolerance of 0.50 ppm for pineapples would be adequate for the juice also.

No conclusions can be drawn concerning the adequacy of the proposed tolerance due to insufficient data. The raw agricultural commodity (rac) for pineapple is the whole fruit with the crown removed. No data have been provided on the rac. Additional residue data are needed at the maximum proposed use level on whole fruit. Data should be representative of various pineapple growing regions in Puerto Rico and varying climatic conditions which occur from year to year. Data are needed on crown, bran, juice, pulp and forage. From the limited data submitted, it appears that the proposed tolerance of 0.50 ppm is too high.

Since the petitioner is requesting a tolerance with regional registration in Puerto Rico only, and since pineapple does not fall under the minor use category as defined in the Federal Register, Vol. 51, No. 63, 4/2/86, additional information should be submitted which would verify that the proposed use meets the 5 criteria listed in this federal register notice on minor uses. The criteria are as follows:

1. Likelihood of expanded use. Information must be provided which would indicate there is little likelihood of use of the pesticide outside of the geographically limited area. Documentation of the known range of the pest is required to show that the pest is not known to occur outside of the proposed use area.

2. Quality of the available residue data. EPA will evaluate whether data from one or two geographic areas reflect more than one growing season and a representative range of growing conditions, ie weather, soil conditions, pH level, and local agricultural practices.

3. Availability of data on similar crops. EPA will use residue data from similar crops if available.

4. Variability of the residue data base. Geographically limited residue data are more likely to be accepted for

pesticide uses that result in no detectable residues, versus uses that result in finite residues that are highly variable. Data for pesticides that are shown to be non-systemic are also more likely to be acceptable than for systemic pesticides.

5. Toxicity of the pesticide. The agency is more likely to accept limited residue data for pesticides which have no special toxicological concerns such as teratogenicity, acute toxicity, delayed neurotoxicity, oncogenicity, etc.

The above criteria have not been adequately addressed in this current submission.

If the proposed use does not qualify as a tolerance with regional registration, residue data will be needed on pineapple fruit, bran, juice and forage reflecting the maximum proposed use from representative pineapple growing areas, including Hawaii.

Pineapple forage is an animal feed item. Data are needed on residues which may occur in forage from the proposed use and a pineapple forage tolerance should be proposed. Alternatively the petitioner may propose a feeding restriction on pineapple forage in lieu of residue data.

Residues in Meat, Milk, Poultry and Eggs

We can draw no conclusions concerning secondary residues in meat, milk, poultry and eggs until additional residue data are submitted at the maximum proposed use level for pineapple bran and forage (if a feeding restriction is not proposed for forage).

Other Considerations

The International Residue Limit Status sheet is attached. There are no established tolerances for fenvalerate (pydrin) in/on pineapples in Canada, Mexico or by Codex therefore ther are no conflicts.

cc: PP#8E3636, E. Haeberer, RF, Circu(7), PMSD/ISB
RDI: Robert Quick, 9/28/88; Richard Schmitt, 9/29/88
eth

INTERNATIONAL RESIDUE LIMIT STATUS

F. Lee
8/4/88

CHEMICAL Fenvalerate (Asana)

CODEX NO. 119

CODEX STATUS:

☑ No Codex Proposal Step 6 or above (on pineapple)

Residue(if Step 8): _____

envalerate

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 8E3636

RCB Reviewer E.T. Haebere

Residue: fenvalerate

Crop(s)	Limit (mg/kg)
pineapple	0.5

CANADIAN LIMITS:

☑ No Canadian limit (on pineapple)

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☑ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES:

Form revised 1986