SEP 25 1985

RESIDUE CHEMISTRY BRANCH, HED
PETITION REVIEW QUICK FORM

FROM: M. Nelson, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: R.S. Quick, Section Head, TPS I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: H. Jamerson P.M. Team 43
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

1. Petition No(s).: 5E3242; Acces. No.: 073485; RCB No.: 959
2. Chemical(s): fenvalerate (ISO); Pydrin® (insecticide)
3. Tolerance Proposal (RAC's & Levels): cranberries, blueberries, currants, gooseberries, huckleberries and elderberries @ 2 ppm
4. Petitioner: IR-4 and Ag Exp Stns of ME, MI, NJ, NC, OR, and WA
5. Tolerance Expression: Parent only. [Note: May need to be revised in future to include metabolites, depending on the outcome of an ongoing inhouse assessment on pyrethroids metabolism.]
6. Established Tolerances: 40 CFR 180.379 (0.02-50 ppm, various r.a.c.'s); FAT's under 21 CFR 193.97 and 561.97.
7. Letter(s) of Authorization (if applicable): 3/13/85 - Shell Oil Co. grants limited access; okay for use of files on EPA Reg Nos. 201-401 (Pydrin® Insecticide 2.4EC) and 201-402 (Technical Pydrin® Insecticide).
8. Formulation(s): Pydrin® Insecticide 2.4EC (EPA Reg No 201-401), an emulsifiable concentrate containing 2.4 lbs ai/gal (30% by weight).
9. Inerts Status: All cleared under 40 CFR 180.1001. (Formulation composition detailed in Sec. A-2, PP# 7F2013.)

10. Manufacturing Process: Detailed in Sec. A-4, PP# 7F2013 and discussed in 5/10/85 review (F. Boyd) of PP# 5F3171. Technical is 92% pure; 23 impurities, each ≤ 0.2%, mainly Pydrin analogs from isomeric impurities in starting materials. These do not constitute a residue problem.

11. Proposed Use(s): Apply 0.1-0.2 lb ai/A (5-1/3 to 10-2/3 fl.oz/A; 1 gal. treats 12-24 A) of Pydrin 2.4EC as needed for insect control, but do not exceed 0.6 lb ai/A/season for caneberries (7-day PHI applies) or 0.8 lb ai/A/season for other berries (listed in #3; 14-day PHI applies).

The following statement should be added to the directions for use: Use in a minimum of X gpa of water (petitioner should propose an appropriate amount) as a full coverage spray. Apply by ground application equipment only.

12. Plant Metabolism Data on: cotton (PP# 6G1755); apples and lettuce (PP# 8G2023 and 8G2024); tomatoes (PP# 0F2367); soybeans (PP# 0F2375); wheat (PP# 4F3120).

13. Plant Residues Comprised of:

All of the plant metabolism studies have shown fenvalerate to be a long lasting chemical that degrades very slowly. Most of the residues are surface deposits indicating limited penetration past the waxy plant surface. Fenvalerate does not translocate in the plant; leaf deposits stay on the leaves. As much as 10% of residue may be found as a photodegradate, 4-chloro-beta-(1-methylethyl)-alpha-(3-phenoxyphenyl) benzene. Less than 10% may be found as any of five different benzeneacetates or phenoxybenzoates, usually conjugated and water solsuble. The predominant residue of Pydrin (80-90%) is the parent compound. All of the metabolism studies have been performed with appropriate mixtures of C^{14}-ring labeled (benzyl or chlorophenyl) compound.

15. Nature of Plant Metabolism Data (is)/is not adequately defined.

The Residue of Concern is: parent compound only. (See #36)

16. Animal Metabolism Data on: Not applicable; no feed items associated with this petition.

17. Animal Residues Comprised of: NA

18. Animal Metabolism Data Applicable Here: NA

19. Nature of Animal Metabolism Data is/is not adequately defined.

The Residue of Concern is: NA

20. Analytical Methods (reference or brief description):

Used in analyzing field study samples:

① EC-GLC Method: MMS-R-478-1, Shell Chemical. Method I in PAM II, Sec. 180.379.

② EC-GLC Method: MMS-R-456-1 (modified), Shell Chemical. Similar in principle to ① above, but different organic solvents utilized for extraction/clean-up.

③ HPLC Method: MMS-R-527-2 (modified), Shell Chemical. Extraction/clean-up very similar to ① above with HPLC vs EC-GLC determinative step.

EC-GLC basic methodology has been successfully MTO'd. For details see discussion in PAM II under Sec 180.379.

21. Method Validation (crop recoveries): for various berries via PARENT COMPOUND

EC-GLC methodology: 0.05-1 ppm fortification; 73-134% recovery

HPLC methodology: 0.1-2.7 ppm fortification; 77-114% recovery

22. Method Validation (control values):

Via EC-GLC methodology: <0.01-0.03 ppm; sensitivity: 0.01-0.02 ppm.

Via HPLC methodology: ND-~~0.2~~<0.5 ppm (two aberrant high values) (reflecting field contamination); sens: 0.04 ppm

23. Residues Determined by Method: Parent compound.

24. Enforcement Methodology (is)/is not available.

25. Residue Data (crop and residue range (ppm) from Proposed Use):

Crop:		
	blueberries raspberries blackberries marionberries boysenberries	residues ranged up to 2.0 ppm under proposed use conditions. Factoring in corrections for recoveries and storage stability, a 2.0 ppm tolerance could be exceeded. See #33.
	WA, OR, MI, ME, NJ, NC, NY sites Ground equipment only	mainly GLC determinations one LV study
	1-10 mos storage 1-7 applications; PHI's: 1-16 days	field contamination of checks reported in NC studies.
	1982-1984 crop years 15 field studies	chromatograms were submitted.

Other Comments: Storage stability data for up to 23 months are available on a variety of r.a.c.'s showing only moderate decline of fenvalerate residues with time. Raspberry and blackberry data submitted with this petition (3-8 months storage) show a significant decline in some of the stability studies.

26. Residues will not exceed proposed tolerance on (commodities)

NA

and ~~will~~ MAY exceed proposed tolerance on (commodities) _____

all berries listed in #3

27. Livestock Feeding Studies on (species): NA

28. Animal Feeding Levels: NA

29. Animal Residue Ingestion Levels from Proposed Crop Tolerance Levels (proposed tol. level x % in diet): _____ ppm in beef cattle; _____ ppm in dairy cattle/goats; _____ ppm in hogs; _____ ppm in horses; _____ ppm in sheep; _____ ppm in poultry.

NA

30. Livestock Tolerances are Adequate in (species) _____, but not adequate in _____

NA

NA

31. Livestock Tolerances Need to be Established: yes/no. If yes (species/levels): _____

32. Other Comments: caneberries are defined in 40 CFR 180.1(h); since fenvalerate is not considered systemic, 40 CFR 180.34(e)(4) applies – i.e., blueberries, currants, gooseberries, and huckleberries are considered related crops. Elderberries are included in the small fruits and berry crop group [40 CFR 180.34(f)(9)(xiii)] and have similar cultural practices to the other berries of this petition, ergo we do not object to their inclusion in the proposed tolerance.

33. Other Considerations: Taking into account the variable recoveries, the losses during storage, "contaminated" checks, and residue values at the proposed tolerance level, we consider a 3.0 ppm proposed tolerance level to be more appropriate. A revised Sec. F is needed.

34. Additional Data Needed: None

35. Recommendations: Negative, pending receipt of a revised Section B (see #11) and Section F (see #33), and provided toxicological considerations permit.

36. Other Comments under Recommendations: The petitioner should be advised that the tolerance expression for fenvalerate residues in/on plant commodities may require revision in the future to include metabolites, depending on the outcome of an ongoing inhouse assessment on pyrethroids metabolism. For the present, parent compound only is considered the residue of concern.

37. Compatability with Codex Tolerances: Incompatible, but residue data (see #25) do not support lowering the proposed tolerance level to 1 ppm for compatability purposes.

cc: RF, Circ, Reviewer, PMSD, ISB, TOX, EEB, EAB, FDA, PP# 5E3242

Approved: Quick R/I RW 9/25/85 ; Schmitt [illegible] 9/25/85

Nelson 7/16

f. Hess 6/4/85

IN RNATIONAL RESIDUE LIMIT STATU

CHEMICAL fenvalerate

PETITION NO 5E3242
Pydin (fenvalerate)

CCPR NO. 119

Codex Status

☐ No Codex Proposal
Step 6 or above

Proposed U. S. Tolerances

for 40 CFR 180.379

Residue (if Step 9): fenvalerate

Residue: fenvalerate

Crop(s)	Limit (mg/kg)
small fruits and berries	1

Crop(s)	Tol. (ppm)
caneberries*, blueberries, currants, gooseberries, huckleberries, elderberries	2 ppm

CANADIAN LIMIT

Residue:

Crop	Limit (ppm)
none (on commodities listed above)	

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm)
none	

Notes: * comprised of blackberries, boysenberries, dewberries, loganberries, raspberries, youngberries.