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

EXPEDITE

AUG 19 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Shell ASANA Insecticide (Fenvalerate or Pydrin SS)
EPA File Symbols 201-URI and 201-URO
[RCB Nos. 1283, 1284; Accession No. 264097]

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As a followup to a meeting held between EPA and Shell, July 23, 1986, Shell Oil Company has submitted Acceptable Daily Intake (ADI) calculations for ASANA Insecticide based on tolerances for those crops that were registered for PYDRIN Insecticide as of July 1984. The submission includes summaries of PYDRIN residue data.

This review is being EXPEDITED at the request of James Akerman, Acting Director, Registration Division. (See letter of August 11, 1986 to John Melone.)

An application for registration of ASANA Insecticide is pending. ASANA technical contains 75% SS isomer of fenvalerate [cyano(3-phenoxyphenyl)methyl- -1-methylethyl-4-chlorobenzene acetate], a synthetic pyrethroid. Shell's currently registered product, PYDRIN, contains a racemic mixture of four stereoisomers in equal concentrations. The SS isomer is insecticidally active. The application rates for ASANA 1.9 EC are the same as the application rates of the SS isomer of PYDRIN in PYDRIN 2.4 EC. Thus, the amount of ASANA active ingredient (predominantly SS isomer) applied per acre is approximately one-fourth the amount of PYDRIN active ingredient applied per acre (all isomers).

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Tolerances for residues of fenvalerate have been established on a variety of raw agricultural commodities including meat and milk at 0.1 to 50 ppm [40 CFR 180.379] and feeds [21 CFR 561.97].

RCB has previously reviewed the application for registration of ASANA 1.9 EC, formerly known as SS PYDRIN 1.9 EC (L. Cheng, 11/26/84 and 7/10/85). RCB recommended for the registration of ASANA (L. Cheng, 7/10/85). A conference was recently held with the registrant (L. Cheng, 7/23/86).

This submission (Accession No. 264097) includes the following:

1. Tabulation of PYDRIN Tolerances which are proposed for ASANA and the percentage of the provisional maximum permitted intake (PMPI) for each crop.

2. "Anticipated Residues" for each crop, based on the 95th Percentile.

3. "Anticipated Residues" and usage in diet for feed items.

4. Estimates of dietary intake for animals, based on "anticipated residues."

5. Calculation of anticipated secondary residues for poultry, cattle, and swine, based on "anticipated residues" for each crop.

6. Tabulation of TAS food factors for the US population, nursing infants, and non-nursing infants.

7. Anticipated residue contribution by commodity and age group in mg/kg.

8. Calculation of PADI utilization, based on "anticipated dietary residues."

9. ASANA Insecticide 1.9 EC label.

10. Technical ASANA Insecticide label

11. Summaries of PYDRIN residue data.

RCB COMMENT

RCB previously concluded that residues of fenvalerate from the use of ASANA Insecticide would be covered by the tolerances currently established for residues of fenvalerate from the use of PYDRIN. (Conference with the registrant,

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7/23/86, L. Cheng). Data included in an earlier submission (L. Cheng, 11/26/84) demonstrated that fenvalerate residues from the use of ASANA on alfalfa, soybeans, and corn, are lower than residues of fenvalerate from the use of PYDRIN on these crops, when ASANA is applied at a rate (in lb ai/A) four times lower than that of PYDRIN. This conclusion can be extended to other crops. We note, however, that fenvalerate residues from the use of ASANA are not necessarily four times lower than fenvalerate residues from the use of PYDRIN.

Calculations of the TMRC are based on tolerance level residues (A. Kocialski, TOX, personal communication, 8/19/86). Calculations based on "anticipated residues" are not appropriate at this time. Consequently, the submission will not be reviewed at this time. The Shell submission will be retained in our files for future reference. We do, however, have several questions about the submission.

1. Define 95 percentile, and show how these values were calculated.

2. Give references (Accession No., date of submission, PP#) for the raw data summarized in the PYDRIN residue data summaries.

CONCLUSIONS AND RECOMMENDATIONS

TOX has indicated that the TMRC is calculated using tolerance level residues (A. Kocialski, personal communication, 8/19/86). We note that tolerances established for residues of fenvalerate from the use of PYDRIN are adequate to cover residues of fenvalerate from the use of ASANA. Since old PYDRIN formulations are still being used, it is not appropriate to recommend the lowering of the tolerances at this time. This should be considered when PYDRIN formulations are discontinued.

cc:R.F., circu, S. Hummel, (W. Greer (TOX), fenvalerate S.F., fenvalerate amended use file, PMSD/ISB
RDI:EZ:8/19/86:RDS:8/19/86
TS-769:RCB:SVH:svh:RM:810:CM#2:8/19/86

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