RF

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

JAN 27 1987

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA Nos. 201-URI and 201-URO: ASANA Insecticide (Active Isomer of Fenvalerate). Procedures for Calculation of Anticipated Residues. No Access. Nos; RCB Nos. 1610, 1611

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Shell Oil Company has applied for the registration of ASANA Insecticide. ASANA contains enhanced levels of the insecticidally active SS isomer of fenvalerate [cyano(3-phenoxyphenyl)methyl-1-methylethyl-4-chlorobenzene acetate]. ASANA has approximately 4 times the concentration of the active isomer as Shell's currently registered fenvalerate, Pydrin. Suggested label application rates of ASANA are thus 1/4th that of Pydrin.

RCB has recommended that ASANA be registered as it considered that residue data supporting the registration of fenvalerate as applicable to ASANA, (L. Cheng, memo of 11/26/84).

As part of the registration process, Shell had calculated dietary exposures for ASANA derived from Pydrin residue data. Shell's submission included the calculation of anticipated residues (AR) for each treated crop based on the 95th percentile of reported pydrin residues. RCB reviewed this submission and re-rcommended:

> The registrant should submit full and complete explanation of how the "anticipated residues" were determined and full and complete calculations of the 95 percentile used in the tables. We recommend that the registrant be so informed. (S. Hummel, memo, 10/2/86)

Shell has replied to RCB's comments by providing an explanation of its use of 95th percentile values as "anticipated residues"

Shell states that the 95th percentile values were calculated as given in Fig. 1 of "The Tolerance Assessment System - Background Information" as pepared by Chaisson et al of TOX Branch, HED. The procedure uses a frequency-cumulative percent analysis to determine the Anticipated Residue (AR).

For commodities where sample numbers were less than 20, an interpolated AR was selected between the highest values found and the tolerance.

In instances where the number of samples were low, additional samples with slightly higher rates and/or lower PHI's were included. Values for apple; sweet corn; cucumbers; melons, pempkins and squash; eggplant; peas; peppers; potatoes; soybeans; and tomatoes fall into this category.

Shell in the current submission also has listed the petition numbers and dates of submission of the Pydrin residue data for the various commodities.

Comment

We do not believe that Shell's response addresses the issue raised in RCB's comment in the 10/2/86 memo. The value of the 95th percentile of residue levels as the anticipated residue was used by Chaisson et al as an example of a value that possibly could be used as the anticipated residue. The use of this value has not been formally accepted by RCB and TOX as the value to be considered the anticipated residue.

RCB, when it requested a fuller explanation from Shell, intended that Shell provide a fuller explanation of the procedure it employed for selecting residue values that were used in arriving at 95th percentile values for each commodity. The Pydrin data base contains residue values for each commodity at various application rates and various PHI's. Shell needs to indicate for each commodity which of these values it chose and the criterion of selection.

As an example, the residue data base contains 32 values for Pydrin residues on whole apples after various application rates and PHI's. Only 1 of these values is derived from a trial at rates and PHI's equivalent to that proposed for ASANA on apples. For apples, Shell lists a mean of 0.56 ppm, a median of 0.62 ppm, and a 95th percentile of 1.1 ppm for ASANA. We cannot readily determine which values were selected to arrive at the listed figures. In fact, the value 0.62 ppm given for the median does not occur in the whole apple residue set.

Conclusion and Recommendation

Shell has not satisfactorily explained the procedure it employed to arrive at the residue values for ASANA that it considers the "Anticipated Residue".

As the the Pydrin data base from which the ASANA values are derived contains residue values for each commodity at various application rates and various PHI's, Shell needs to indicate for each commodity which of these values it chose and the criterion of selection.

cc: R.F., S.F., Amend Use F., Circ., Reviewer, PMSD/ISB
RDI:ARR: 1/20/87:RDS: 1/21/87
TS-769:RCB:JG:jg:CM#2:Rm.803a:557-1439: 1/22/87