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

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

FEB 09 1982

SUBJECT: PP#1G2461, FAP#1H5287. Cypermethrin on cotton. Evaluation of amendment dated 9/9/81 including revised Sections B and F.

FROM: Andrew Rathman, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Franklin D.R. Gee, Product Manager #17
Insecticide-Rodenticide Branch
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

This amendment is in response to the F. Gee reject letter dated 5/20/81 based upon the RCB memo dated 4/24/81. The deficiencies are listed below in the order they appeared in the reject letter followed by the petitioner's response and our comments.

Deficiency 1 - While the manufacturing process has been submitted, analyses of the technical product was not provided. This information is needed along with the purities of the starting and reaction products.

Petitioner's response - This information is now being submitted. The composition of the technical product is attached at the end of this memo.

Our comments - We consider the submitted data acceptable. We do not believe there will be a residue problem with the impurities present in the technical product.

Deficiency 2(a) - We do not have enough information to determine the adequacy of the methods used to obtain the residue data. We will need the following:

A. The "PPRAM-42" method.
B. Details of the method used by ABL that should have been included as Appendix 2 of Ref. 5D.
C. Representative chromatograms

Petitioner's response - This information in now being submitted. The method used by ABL involves extraction of the sample with a 50/50 mixture of petroleum ether/acetone. The solution is evaporated and the remaining oil is dissolved in methylene chloride/cyclohexane (15/85). The sample is then processed through a GPC Auto Prep 1001 using a biobead SX-3 column.

The sample is further cleaned-up on a Florisil column determined by ECGC using decamethrin as an internal standard (added after clean-up). Submitted chromatograms indicate a sensitivity of at least 0.05 ppm.

Our comments - We now consider this procedure acceptable for obtaining residue data. The enforcement procedure was discussed in our 4/24/81 review and is acceptale for enforcement purposes.

Deficiency 2(b) - No method has been submitted for determination of residues in meat and milk. Such a method is needed.

Petitioner's response - A method has been developed and is included in this submission. The method (No. 56) is entitled "The Determination of Residues of Cypermethrin in Products of Animal Origin." The procedure is very similar to the enforcement procedure for cottonseed. Samples (milk or tissues) are extracted with 50% v/v acetone:hexane in the presence of granular sodium sulfate (tissues) or potassium oxalate (milk). The extracts are washed with water to remove acetone and co-extracted lipids are removed with acetonitrile/hexane liquid-liquid partitioning. Tissue samples are further cleaned-up on a Florisil column. Determination is by ECGC compared against an internal standard (decamethrin) added prior to extraction. Samples of milk, muscle and fat fortified at levels of 0.2, 0.49 and 2.4 ppm respectively had recoveries ranging from 93-107%. The senstivity of the method is at least 0.01 ppm for milk and 0.02 ppm for tissues.

Our comments - We consider this method acceptable for this limited EUP. For any permanent tolerance request for residues in meat and milk, we will require a method that does not use internal standardization. Additionally, validation data for the method without internal standardization will be required.

Deficiency 3 - No storage stability data were submitted. We need data showing that residues are stable for periods up to seven months.

Petitioner's response - Three separate storage stability studies have been submitted. The first study is with field treated apples and cabbage stored at - 18 C for 12 months. The second study is with fortified apples, lettuce and soil stored at - 18 C for 12 months and the third study is the reanalyses of cottonseed which had been stored for 6 months at -23 C.

2

Results from all these studies show essentially no loss of residues with time.

Our comments - We consider these data acceptable to resolve the deficiency.

Deficiency 4(a) - No final conclusion can be made on the acceptability of the residue data for cottonseed because of 2(a) and 3 above; however, if these problems are resolved, we still would not be able to consider the data adequate to support the requested tolerance. We suggest the proposed cottonseed tolerance be increased to 0.5 ppm. Additionally, the cottonseed treated at the high (0.5 lb ai/A) rate should be destroyed.

Petitioner's response - Section F has been revised to request a tolerance of 0.5 ppm for cypermethrin residues in or on cottonseed. Section B has been revised and now states that cottonseed treated at rates higher than 0.125 lb ai/A must be destroyed.

In addition to the changes in Sections B and F, the results of 12 field trials have been included. In all of these studies, 16 applications of cypermethrin were made at rates of 0.12-0.48 lb ai/A. PHI's ranged from 13-31 days. Residues from the 0.12 lb rate (1X) ranged from 0.01-0.31 ppm. Residues from the 0.24-48 lb rates ranged from 0.01-0.52 ppm.

Our comments - The new data support our contention that the 0.5 ppm level is appropriate. We consider this deficiency resolved.

Deficiency 4(b) - Until 4(a) above is resolved, we can make no final conclusion concerning cottonseed by-products; however, it appears that a food additive tolerance of 5 ppm is needed for refined oil and the request for the cottonseed hulls should be withdrawn.

Petitioner's response - Section F has been revised to propose a 5 ppm food additive tolerance for oil and the hull request has been deleted.

Our comments - We consider this deficiency resolved.

Deficiency 5 - We consider this use to fall into Category 2 of Sec. 180.6(a). Tolerances are needed for residues in meat and milk at 0.01 ppm.

Petitioner's response - Tolerances have been proposed at 0.05 ppm for residues in meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep and in milk.

Our comments - While the tolerance request is higher than necessary, we are raising no objections in connection with this EUP and consider the deficiency resolved.

3

Conclusions

1. Adequate methods are available for enforcement purposes.

2(a). Residues from the proposed use will not exceed the requested 0.5 ppm tolerance for residues in cottonseed.

2(b). The 5 ppm tolerance for residues in oil is appropriate and adequate.

3. The requested meat and milk tolerances are acceptable.

Recommendation

We recommend for the proposed tolerances for residues of cypermethrin noted below:

0.5 ppm in or on cottonseed
0.05 ppm in the meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep and in milk
and the following food additive tolerance:
5 ppm in cottonseed oil

For any permanent tolerance, we will need large animal metabolism and feeding studies. Additionally, for any proposal for residues in meat and milk, we will need a method which does not utilize internal standardization along with appropriate validation data.

Attachment

cc: Reading file
Circu
Reviewer
FDA
PP# No.
EEB
EFB
TOX
Randy Watts

TS-769:Reviewer:A.Rathman:LDT:X77324:CM#2:RM:810:Date:2/9/82
RDI:Section Head:RJH:Date:2/4/82:RDS:Date:2/4/82

Cypermethrin Review

Page _____ is not included in this copy.

Pages 5 through 6 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

X The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.