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

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MAY 29 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: FAP#6H5515 - Cyfluthrin in Food-Handling Establishments - Evaluation of Analytical Methods and Residue Data - Accession Nos. 264523, 264525 (No MRID Number) - RCB Nos. 2291, 2292

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and

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THRU: Charles L. Trichilo, Chief
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Mobay Chemical Corporation is proposing the establishment of tolerances for the insecticide Tempo® (cyano-(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethyl cyclopropanecarboxylate, cyfluthrin, Baythroid®) in foodstuffs at 0.05 ppm from the use of cyfluthrin in food-handling establishments.

No permanent tolerances have been established for cyfluthrin. However, RCB recommended for tolerances for cyfluthrin per se on cottonseed at 1 ppm, meat at 0.05 ppm, milk at 0.01 ppm, and cottonseed oil and hulls at 2 ppm (see K. Arne memorandum dated February 14, 1985, PP#4F3046/4H5427).

Temporary tolerances have been established on cotton, peanuts, and soybeans (PP#4G2976/4H5416). Temporary petitions 4G3126 (corn and potatoes), 5G3193/5H5452 (alfalfa, broccoli, Brussels sprouts, cabbage, and cauliflower) and 4G3259/5H5470 (tomatoes) are currently in reject status. Temporary tolerances for pears and apples were recommended (see L. Propst memorandum dated Decembr 23, 1985, PP#6G3307).

Conclusions

1. There is no formal means of clearing inert ingredients for food additive use. Therefore, we defer to TB as to the safety of the use of the inerts in the proposed formulation (See Confidential Appendix).

2. Note 3 on the revised labeling (November 10, 1986 Draft) should be revised to reflect a 0.1% active ingredient (ai) concentration.

3. The nature of the residue in food-handling establishments is understood for the proposed use. The residue of concern is cyfluthrin per se.

4a. Adequate analytical methods will be available for the determination of cyfluthrin per se in plant and animal commodities from PMSD when tolerances in PP#4F3046 are established.

b. The petitioner needs to comply with the Residue Chemistry Data Requirements in 40 CFR 158.125(b)(15) regarding the testing of pesticide chemicals through the Food and Drug Administration (FDA) multiresidue methods. The protocols for the tests were published as Appendix II to the Pesticide Analytical Manual - Volume I (PAM-I) January 1987. The FEDERAL REGISTER Notice, 51 FR 34249, of September 26, 1986 gives additional information on the testing.

c. Confirmatory methods, Mobay Report Nos. 86232 and 87462, have been submitted that separate cyfluthrin from cypermethrin and permethrin, two closely related compounds. Clean, nonconfidential, nonstamped "property of" copies of these two confirmatory procedures should be submitted for publication in the Pesticide Analytical Manual, Vol. II (PAM-II).

5a. Residues of cyfluthrin are not likely to exceed the proposed tolerance of 0.05 ppm (limit of detection) on foods or feeds from the proposed use where food is to be removed or covered in food-handling establishments as listed in Table I of the Residue Chemistry Guidelines.

b. The submitted residue study is not applicable to the proposed uses in graineries, greenhouses, trucks, trailers, railcars, and vessels where food may be grown or bulk food or feed may be stored or transported. These uses are not considered food-handling establishment uses and should be removed from the label or supporting data should be submitted.

6. Food-processing plants handle animal feed items as well as human foods. Although no problem is expected from secondary residues in animal products from treated feed because no residues are expected in the feed, a feed additive regulation should be proposed for this use. Both food and feed additive regulations should be proposed including the tolerance and specifications of use such as maximum application rate and types of treatment (general surface, crack and crevice, spot). Examples may be found in 21 CFR 193 and 561, especially 193.85, 193.375, 561.415, and 561.434.

7. An International Residue Limit Status sheet is attached as Appendix I. There are no Codex proposals Step 6 or above and no Canadian or Mexican limits for cyfluthrin.

Recommendations

We recommend that the proposed tolerances not be established because of Conclusions 1, 2, 4a, 4b, 4c, 5b, and 6.

Note to PM: These tolerances and regulations are dependent on the tolerances and methodology in PP#4F3046 and should not be established until regulations for PP#4F3046 are established.

Detailed Considerations

Manufacture and Formulation

The manufacturing process and information regarding technical impurities were submitted in PP#4G2976 and 4F3046. For the discussion of this information, see the April 17, 1984 R. Loranger memorandum, PP#4G2976, and memorandums of K. Arne, PP#4F3046.

[redacted] All of the inert ingredients in this formulation have been cleared under 180.1001(c) for use on raw agricultural commodities. However, there is no formal means of clearing inerts for food additive use. Therefore, we defer to TB as to the safety of the inert ingredients listed in the Confidential Appendix to this review for this use.

Proposed Use

An amendment to Section B was submitted November 26, 1986, with label directions for use of a 9.5 g packet of 20% ai. The product is intended for use by professional applicators for pest control in and around buildings and structures and their immediate surroundings and on modes of transport including trucks, trailers, railcars, and vessels.

Food-handling establishment uses include general surface application to walls, floors, and ceilings, and around equipment and floors at 1.9 g/ai/1000 sq ft or 3.8 g/ai/1000 sq ft under conditions of severe pest infestation. One (1.9 g/ai) or two (3.8 g/ai) packets are used in sufficient water, 0.25 to 48.5 gal depending on type of surface, to cover the area to the "point" of runoff.

Crack and crevice or spot treatments are to be applied as 1.9 g/ai/gal of water (0.05% ai) with a low-pressure system with a pinpoint or variable pattern nozzle to specific crack, crevice, or spot not exceeding 2 sq ft in any one area. Under severe pest infestations, 3.8 g/ai/gal or 0.1% ai may be used. Note 3 on revised labeling should be corrected.

For food-handling establishment uses, reapplication may be made at 10-day intervals. Food is to be covered or removed during treatment.

Nature of the Residue

Plant metabolism studies in cotton, soybeans, and apples have been submitted and show that the majority of the residue is the parent compound although the metabolites dichloroethenyl-2,2-dimethylcyclopropane carboxylic acid (DCVA), 4-fluoro-2-phenoxybenzaldehyde (FPB ald) and the corresponding acid (FPB acid) and alcohol (FPB alc) have been detected.

For the purposes of this food-handling establishment use the residue of concern is cyfluthrin per se because little if any metabolism would occur, there is no direct contact, and the length of indirect exposure is usually minimal.

Animal metabolism studies have been submitted for cows, hens, and rats. The major residue in milk, cattle muscle, and fat is cyfluthrin. In bovine heart and kidney, the parent compound represented 71 and 56%, respectively, while FBP alc accounted for 29 and 43%, respectively. Cyfluthrin residues in poultry muscle were 21 to 39% of the residue with FPB acid and FPB alc as the major residue. The parent compound was 56% of the residue in eggs.

Reexamination and evaluation of residues in beef liver have demonstrated that the parent compound is an important residue in the liver (K. Arne memorandum dated February 14, 1985, PP#4F3046). K. Arne's review also states that additional uses that involve feed items may require inclusion of metabolites in the tolerance expression for animal tissues as well as development of appropriate methodology.

For the purposes of this use where no residues are expected, the residue of concern in animals is cyfluthrin per se.

Analytical Method

The method used to determine cyfluthrin per se is Mobay Report No. 91954 dated April 2, 1986 (clean copy in Correspondence Folder). Extraction is with acetone/chloroform followed by a water partition and/or a hexane/acetonitrile partition and deactivated Florisil cleanup. Various techniques are used depending on the oiliness of the commodity. Detection is by gas chromatography using a capillary column or an alternate chromosorb W column and an electron capture detector.

The various steps in the method were checked for completeness of recovery by fortification with phenyl-UL-^{14}C cyfluthrin. Recoveries ranged from 82 to 100% at 0.1 ppm when analyzed shortly after fortification. When hamburger was fortified and allowed to stand for 1 and 2 hours before extraction, recovery of 66 and 71%, respectively, was found. (The hamburger from the residue test was analyzed immediately after the test.) Recovery of unlabeled cyfluthrin in bologna, bread, flour, hamburger (raw), lettuce, macaroni, peaches (no pit), rice cereal, sugar, milk, and butter ranged from 76 to 118% at 0.1 ppm fortification, 62 to 88% at 0.05 ppm fortification, and from 0 to 130% at 0.01 or 0.02 ppm fortification. Controls were equal to or less than 0.05 ppm, the limit of determination of the method.

Except for the various extraction techniques, this method is very similar to Mobay Report No. 85823 for which a successful method tryout (MTO) was conducted on cotton. The MTO for Mobay Report No. 85883 on meat, milk, and eggs was also successful (PP#4F3046/4H5427). The methods determine cyfluthrin per se.

Confirmatory methods, Mobay Report Nos. 86232 and 87462, have been submitted that separate cyfluthrin from cypermethrin and permethrin, two closely related compounds. Clean, nonconfidential, nonstamped "property of" copies of these two confirmatory procedures should be submitted for publication in PAM-II.

We conclude that there are adequate methods for cyfluthrin per se and they will be available from PMSD when tolerances associated with PP#4F3046 are established.

The petitioner will need to comply with the Residue Chemistry Data Requirements of 40 CFR 158.125(b)(15) regarding the testing of pesticide chemicals through the FDA multiresidue methods. The protocols for the tests were published as Appendix II to PAM-I, January 1987. FEDERAL REGISTER Notice, 51 FR

34249, of September 26, 1986, gives additional information on the testing.

Residue Data

Storage stability studies have been submitted for cattle tissues, soybeans, and soybean hay. There was no significant degradation of parent compound in kidney or liver at fortification of 10 ppm at about 30 and 90 days of frozen storage. No degradation was noted in soybeans or soybean hay fortified at 1 ppm at 96 days (beans) or 91 days (hay). (See K. Arne memorandum dated January 25, 1985, PP#4F3046.) Additional storage stability studies are requested for the commodities in PP#5G3193 for permanent tolerances (M. Firestone, May 3, 1985).

For the present submission, raw hamburger and butter were processed immediately after the test and the remaining commodities were analyzed within 1 week, storage under freezer conditions, after sampling.

The storage stability data are considered adequate to support the proposed tolerances.

The residue study was conducted as a general surface treatment in a simulated food handling establishment. The spray solution was prepared from Tempo 2 formulation at a rate of 3.7 g/ai/1000 sq ft or 97.3% of the newly recommended 3.8 g/ai/1000 sq ft. All walls, doors, windows, fixed sinks, and drains, as well as a portion of the ceiling, were sprayed for a total of 1770 sq ft.

Food items, wrapped and unwrapped, were present during the treatment and 30 minutes after the treatment. Other sets of food were exposed to the room on carts present during the treatment and on carts not present during the treatment. The latter foods were left for periods up to 24 hours.

Bologna, bread, butter, flour, macaroni, milk, rice cereal, and sugar were exposed in original wrappers to the treatment and contained no detectable (< 0.05 ppm) residue. Bread, butter, flour, raw hamburger, lettuce, macaroni, milk, peaches, rice cereal, and sugar were exposed without wrappers to the treatment and residues ranged from 0.09 ppm in flour to 3.42 ppm in bread.

The same food items exposed to volatile residues, both wrapped and unwrapped, on clean carts and contaminated carts, for 0.5 to 24 hours after treatment, had no detectable (< 0.05

ppm) residues. Not all foods for every time interval and condition of exposure were analyzed; however, enough representative samples, including bread and butter unwrapped, were analyzed to show that residues are not likely to occur from this use in food service, manufacturing, and processing establishments as listed in Table I of Residue Chemistry Guidelines.

The residue study is not applicable to the proposed uses in graineries, greenhouses, trucks, trailers, railcars, and vessels where food may be grown or bulk food may be stored or transported. These uses are not considered food-handling establishment uses and should be removed from the label or supporting data should be submitted.

Other Considerations

Food-processing plants handle animal feed items as well as human foods. Although we would not expect any problem of secondary residues in animal products from treated feed because no residues are expected in the feed, a feed additive regulation should be proposed for this use. Both the food and feed additive regulations should include the tolerance and the specifications of use such as maximum application rate and types of treatment (general surface, crack and crevice, spot). Examples may be found in 21 CFR 193 and 561, especially 193.85, 193.375, 561.415, and 561.434.

These regulations should not be established until the cottonseed, meat, and milk tolerances associated with PP#4F3046 are established.

Attachments: Appendix I, Codex Sheet
Confidential Appendix II

TS-769:RCB:MBradley:CM#2:Rm810:5577484:5/14/87
cc with Appendix I and II: PMSD/ISB, RF, MBradley, PM15, FAP6H5515, TOX.
cc with Appendix I: Circulate

RDI:Quick:05/20/87:Schmitt:05/20/87.
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APPENDIX I TO FAP#6H5515

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Cyfluthrin

CODEX NO. 157

CODEX STATUS:

|x| No Codex Proposal Step 6 or above

Residue (if Step 8): _____

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 6H5515

RCB Reviewer MJB

Residue: Cyfluthrin

Crop(s)	Limit (mg/kg)
All foods and feeds	0.05

CANADIAN LIMITS:

|x| No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

|x| No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES:

Form revised 1986

CONFIDENTIAL APPENDIX II to FAP#5515

[redacted]

CONFIDENTIAL APPENDIX 2291, 2292
to RCB Science Review No. .....

(Contains FIFRA Trade Secret/CBI Information)

INFORMATION WHICH MAY REVEAL INERT INGREDIENTS IS NOT INCLUDED