ORB (#128831)
9-25-96

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 9/25/96

SUBJECT: **ID# 011556-00113 and ID# 011556-00111.** Cyfluthrin in/on Swine Premises. Request for Amended Registration to Add Use in Swine Premises with the Animals Present.

DP Code: D222630, D222635

Case #: 001607, 038969
Chem #: 128831
Caswell: 266E

Class: Insecticide

Trade Names: Countdown® WP Premise
Countdown® WP Premise in Packets
Reg #: 11556-111 and 11556-113
40 CFR: §180.436
MRID#'s: 438779-01, 438779-02,438779-03

TO: G. Larocca, PM Team 13
Insecticide-Rodenticide Branch
Registration Division (7505C)
And
Deborah McCall
Registration Section
RCAB (7509C)

FROM: José J. Morales, William Dykstra, Charles Lewis
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Health Effects Division (7509C)

José J. Morales 9/25/96

THRU: Michael Metzger, Acting Branch Chief
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Michael S. Metzger

INTRODUCTION

Bayer Corporation, Agriculture Division, Animal Health, is submitting an application to amend the registration of Countdown® WP Premise Insecticide and Countdown® WP Premise Insecticide in Packets to add use in swine premises with the animals present.

Tolerances have been established under 40 CFR §180.436 for residues of cyfluthrin [cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate] in numerous plant commodities with tolerances ranging from 0.05 to 4.0 ppm; in the fat, meat and meat byproducts of cattle, goats, hogs, horses and sheep at 0.40 ppm; milkfat at 2.5 ppm (reflecting 0.08 ppm in whole milk); and poultry fat, meat and meat byproducts and eggs at 0.01 ppm. Food and feed additive tolerances of 0.05 ppm have also been established as a result of use of cyfluthrin in food/feed handling establishments and are listed in 40 CFR §185.1250 and §186.1250, respectively.

RECOMMENDATION

HED cannot recommend for the amended registration for cyfluthrin use in swine premises with the animals present. In the absence of radiolabeled metabolism data or feeding studies showing levels of metabolite DCVA (3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylic acid) in animal commodities, insufficient data are available to conduct dietary risk assessment calculations. Also, new feeding studies and a revised Section B are needed as stated under Dietary Exposure Conclusions 1 and 4.

Occupational exposure should not be increased by the addition of swine facility treatment to the existing labels. RD should insure that the appropriate Worker Protection Standard (WPS) information appears on the labels.

HED notes that the Food Quality Protection Act of 1996 has amended and strengthened FIFRA's "unreasonable adverse effects" standard and thus tightened the requirements for registration under FIFRA. OPP is still assessing the full impact of this change in the law on the registration process and plans to issue guidelines concerning registration requirements. Any new registrations will have to meet the requirements of FIFRA as amended by the FQPA and OPP may require additional data to determine if the terms of the amended statute are met. Our review of this registration indicates that it clearly would have been disapproved under FIFRA prior to its recent amendment. Since FQPA has raised the standard for registration, it is not necessary to conduct a full review under the new statute. The registrant is advised that at such time as the Agency issues guidelines concerning registration requirements, additional deficiencies may need to be addressed.

CONCLUSIONS

Hazard Assessment

1. Occupational Exposure Endpoint Selection

   a) Short- and Intermediate-Term Dermal Risk. For short- and intermediate-term dermal MOE calculations, the Ad Hoc TES Committee [SAB Chief, TB II Chief, TB I Chief, TB II Section Head, TB II Section Head, TB I reviewer, pirat toxicologist] recommended use of the dermal toxicity NOEL of 250 mg/kg/day [highest dose tested] from the 21-day dermal rabbit toxicity study (MRID No. 00131527). There was no LEL in the study.

   b) Short- and Intermediate-Term Inhalation Risk. For short- and intermediate-term inhalation MOE calculations, the Ad Hoc TES Committee [same as above] recommended use of the NOEL of 0.00059 mg/L [0.15 mg/kg/day] from the inhalation developmental study (MRID No. 40968501). At the LEL of 0.0011 mg/L [0.29 mg/kg/day], there were unspecified sternal anomalies and increased incidence of runts.

   c) Chronic Risk. Chronic MOE calculations have not been done, since a chronic exposure scenario does not exist for this use pattern.

   d) Cancer Risk. Cyfluthrin has not been classified as a carcinogen by the Cancer Peer Review Committee.

   e) Dermal Penetration. The default value of 100% is being used for dermal penetration in the absence of actual data.

2. Dietary Endpoint Selection

   a) Acute Dietary Risk. 20 mg/kg/day. For acute dietary risk assessment, the Ad Hoc TES Committee [same as above] recommended use of the NOEL of 20 mg/kg/day, based on resorptions (MRID No. 42675401) at the LEL of 60 mg/kg/day, from the oral developmental study in rabbits. This risk assessment will evaluate acute dietary risk to pregnant females 13+ and older.

   b) Chronic Dietary Risk. RfD = 0.025 mg/kg/day. The RfD was established based on the rat chronic feeding/carcinogenicity study (MRID No. 00137303) with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100 based on decreased body weight in males and inflammatory foci in the kidneys of females at the LEL of 7.5 mg/kg/day.

c) Cancer Risk. Cyfluthrin has not been classified as a carcinogen by the Cancer Peer Review Committee.

Occupational Exposure

Based on the use pattern sought, there should be no increase in worker exposure over currently registered uses of cyfluthrin.

Toxicology data are not available to PIRAT for the proposed formulations. RD should insure that the appropriate WPS information appears on the proposed labels. In addition, the labels provided with the submission state: "Wear safety glasses, goggles, or a face shield when handling the undiluted material and wear a respirator when making general surface, overhead application." These statements are not in the appropriate WPS terminology.

Dietary Exposure

1. The HED Metabolism Committee concluded at its 8/12/96 meeting that tolerances should be set in terms of parent cyfluthrin only. It was also concluded that metabolite FPB and its conjugates are not of concern based on toxicology data for FPB. In the absence of toxicology data, the cis and trans isomers of metabolite DCVA (3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylic acid) are considered to be of comparable toxicity to the parent. Therefore, risk assessment should include cis and trans-DCVA. There are no radiolabeled metabolism data or feeding studies showing levels of DCVA in animal commodities. In the absence of these data, the petitioner is required to submit new feeding studies where residues of cis and trans DCVA and parent cyfluthrin are reported.

2a. Adequate enforcement methodology is available to enforce the tolerance expression. Analytical methodology [Mobay Report 85883: "An Analytical Method for Baythroid in Bovine and Poultry Tissues, Milk, and Eggs", EPA MRID #403015-02, GC/ECD, Limit of Detection is 0.01 ppm] for enforcing cyfluthrin tolerances in animal commodities, has also undergone successful PMV [PP# 4F3046], and been forwarded [3/88] to FDA for inclusion in PAM II.

2b. Cyfluthrin has been analyzed using the FDA multiresidue protocols. According to the FDA Pestrack database, it can be completely (>80%) recovered using protocol A (see also 12/4/87 memo of M. Bradley, PP# 4F3046).

3. Residues of cyfluthrin are not expected to exceed 0.40 ppm in swine meat, meat by-products and fat as a result of the proposed use.

4. The established tolerances for residues of cyfluthrin in/on hogs meat, fat, and meat by-products are 0.4 ppm each. These tolerances are adequate to cover secondary residues arising from the proposed use. The petitioner needs to submit a revised Section B proposing a preslaughter interval of 1 day. Also, the statement: "When used in poultry houses, do not apply while the birds are present" should be removed from the label.

5. PIRAT concludes that in the absence of radiolabeled data or feeding studies showing residue levels of DCVA, we cannot make any dietary estimates for residues of cyfluthrin and DCVA in animal commodities. Therefore, a dietary risk assessment will not be conducted.

DETAILED CONSIDERATIONS

DIETARY EXPOSURE

Product Chemistry

The manufacturing process of technical grade cyfluthrin has been previously described and found to be acceptable (see PP# 4F3046, 5/18/84 memo of K. Arne). None of the actual or theoretical impurities are expected to cause residue concerns.

Proposed Use

Two registered cyfluthrin formulations are proposed for use: Countdown® WP Premise Insecticide and Countdown® WP Premise Insecticide in Packets. Countdown® WP Premise Insecticide (EPA Reg. No. 11556-111) and Countdown® WP Premise Insecticide in Packets (EPA Reg. No. 11556-113) are wettable powders containing 20% ai and 80% of inerts.

The registrant proposes use of Countdown® WP Premise Insecticide for general surface application: use two level scoopfuls (3.8 gr ai) per 1000 sq. ft. in sufficient water to adequately cover the area being treated but which will not allow dripping or run-off to occur. Applications can be made to walls, floors, ceilings, in and around cupboards, between, behind and beneath equipment, appliances, around floor drains, window and door frames, and on the underside of shelves, drawers and in similar areas. Applications may be made to floor surfaces along walls and around air ducts, however, do not treat entire area of floor or floor coverings. All food processing surfaces and utensils should be covered or thoroughly washed following treatment. Cover exposed food or remove from area being treated. Re-application in swine premises with animals present should not exceed a total of 3 treatments at 21-day intervals. For all other uses, re-application can be made at 10-day intervals, if necessary. Cattle, horses, and poultry may be present at time of treatment. Do not apply

directly to animals, feed, food, or watering equipment. When used in poultry houses, do not apply while the birds are present.

The registrant proposes use of Countdown® WP Premise Insecticide in Packets for general surface application: use two packets (3.8 gr ai) per 1000 sq. ft. in sufficient water to adequately cover the area being treated but which will not allow dripping or run-off to occur. Applications can be made to walls, floors, ceilings, in and around cupboards, between, behind and beneath equipment, appliances, around floor drains, window and door frames, and on the underside of shelves, drawers and in similar areas. Applications may be made to floor surfaces along walls and around air ducts, however, do not treat entire area of floor or floor coverings. All food processing surfaces and utensils should be covered or thoroughly washed following treatment. Cover exposed food or remove from area being treated. Re-application in swine premises with animals present should not exceed a total of 3 treatments at 21-day intervals. For all other uses, re-application can be made at 10-day intervals, if necessary. Cattle, horses, and poultry may be present at time of treatment. Do not apply directly to animals, feed, food, or watering equipment. When used in poultry houses, do not apply while the birds are present.

Nature of the Residue

The HED Metabolism Committee concluded at its 8/12/96 meeting that tolerances should be set in terms of parent cyfluthrin only. It was also concluded that FPB and its conjugates are not of concern based on toxicology data for FPB. In the absence of toxicology data, the cis and trans isomers of DCVA (3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylic acid) are considered to be of comparable toxicity to the parent. Therefore, risk assessment should include cis and trans-DCVA. There are no radiolabeled metabolism data or feeding studies showing levels of DCVA in animal commodities. In the absence of these data, the petitioner is required to submit new feeding studies where residues of cis and trans DCVA and parent cyfluthrin are reported.

Analytical Methodology

Analytical methodology [Mobay Report 85883: "An Analytical Method for Baythroid in Bovine and Poultry Tissues, Milk, and Eggs", EPA MRID #403015-02, GC/ECD, Limit of Detection is 0.01 ppm] for enforcing cyfluthrin tolerances in animal commodities is available, has also undergone successful PMV [PP# 4F3046], and been forwarded [3/88] to FDA for inclusion in PAM II.

The petitioner stated that the analytical method used in support of this proposed use was a modification of Mobay Report 85883. Validation for the method was submitted in the following report:

"Cyfluthrin - Residue Analytical Methods (Swine Tissue)"; T. B. Waggoner; 11/13/91; Project No. CYF91B and CYF91B1. Performing Laboratory was M. C. Bowman and Associates, Arkansas (MRID# 438779-01).

Samples of liver, kidney, muscle, fat, and skin were chopped and fortified with 0.05 ppm cyfluthrin added in acetone. Samples were analyzed using GC with ECD. The average percent recovery for swine liver was 92.8%, for swine kidney was 92.8%, for swine muscle was 92.8%, for swine fat was 90.4%, and for swine skin was 89.2%. Submitted chromatograms show well resolved peaks in support of the data.

Cyfluthrin has also been analyzed using the FDA multiresidue protocols. According to the FDA Pestrack database, it can be completely (>80%) recovered using protocol A (see also 12/4/87 memo of M. Bradley, PP# 4F3046).

Residue Data

Residue data were submitted in the following reports:

"Residue Levels of Cyfluthrin in Tissues Resulting From Treatment of Swine Premises with Cyfluthrin Premise Spray: Animal Part"; M. L. Kohlenberg; 12/2/91; Study No. TR-91G-018; Test Facility was Miles, Inc. Agriculture Division, Animal Health Products (MRID# 438779-02).

"Residue Levels of Cyfluthrin in Tissues Resulting from Treatment of Swine Premises with Cyfluthrin Premise; Spray: Analytical Part"; M. C. Bowman; 1/7/93; Study No. TR-91G-018; Performing Laboratory was M. C. Bowman and Associates (MRID# 438779-03).

The study was conducted using twenty young feeder pigs. Twenty-seven grams of a 20% cyfluthrin solution was mixed with sufficient water to spray the area where the pigs were housed. Applications were made to the walls, ceiling and floor in which the animals were housed. Animals were present during application but not sprayed directly with the formulation. All surfaces except the automatic waterers were sprayed until moist but not dripping. The applications were conducted at 3 intervals: day 0, day 21, and day 35. The interval between applications was 21 days between the first and the second application and 14 days between the second and third application. After the first application (day 0) one animal was euthanized on days 3, 5, and 7. After the second application (day 21) one animal each was euthanized on days 24, 26, and 28. After the third application (day 35) three animals each were euthanized on days 38, 40, and 45. The entire liver, both kidneys, composite fat (subcutaneous, omental, and renal), a composite (shoulder, loin, and ham) sample of muscle, and skin were removed from the animals for analysis. After collection samples were frozen (-20°C) and sent to M. C. Bowman and Associates, AR, for analyses.

The residue data indicates that cyfluthrin residues in swine muscle ranged from <0.0005 ppm to 0.0032 ppm; in liver <0.0004 ppm; in fat from 0.006 ppm to 0.043 ppm; in skin from <0.0032 ppm to 0.019 ppm; and in kidneys from <0.0004 ppm to 0.0052 ppm.

The established tolerances for residues of cyfluthrin in/on hogs meat, fat, and meat by-products are 0.4 ppm each. These tolerances are adequate to cover secondary residues arising from the proposed use. The petitioner needs to submit a revised Section B proposing a preslaughter interval of 1 day. Also, the statement: "When used in poultry houses, do not apply while the birds are present" should be removed from the label.

cc: José J. Morales, Charles Lewis, Bill Dykstra, PIRAT, TOX (M. Copley), OREB (#128831), Caswell File (#266E).

7509C: RCAB: PIRAT: CM2: Rm 804 B: 305-5010: 9/25/96
RDI: PIRAT (9/25/96)