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

MAY 31 1991

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Amended Registration. Cyfluthrin: Countdown EC, Countdown WP and Countdown WP in Packets Premise Insecticides. EPA File Symbol(s) 11556-RRE, 11556-RRR and 11556-RRG. (No MRID No; DEB No(s). 7744, 7745 and 7746).
DP Barcode. D162020

FROM: Dennis McNeilly, Chemist *Dennis McNeilly*
Special Review Section II
Chemistry Branch II-Reregistration Support
Health Effects Division (H7509C)

THROUGH: Francis B. Suhre, Section Head *Francis B. Suhre*
Special Review Section II
Chemistry Branch II-Reregistration Support
Health Effects Division (H7509C)

TO: John Hebert, PMT-15
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Mobay Corp., Animal Health Division requests registration of Countdown EC(WP) Premise Insecticide to control crawling and flying insect pests in and around cattle and horse premises. The active ingredient in these products is cyfluthrin [cyano(4-fluoro-3-phenoxyphenyl) methyl 3-(2,2-dichloroethenyl)-2,2-dimethyl cyclo-propanecarboxylate]. The Countdown WP formulations are currently registered under EPA Reg. No. 3125-380 known as Tempo 20WP. The Countdown EC formulation is currently registered under EPA Reg. No. 3125-356 (Tempo 2) and 3125-372 (Tempo 20WP). Tempo 2 is also known as Baythroid®. Countdown WP and EC formulations contain cyfluthrin at 20% and 24.3% respectively, as the active ingredient. Countdown WP in packets (11556-RRG) is the same product as Countdown WP (1156-RRG), however it is packaged in pre-measured 9.5g quantities. Countdown EC is a liquid concentrate which contains 2 lbs. a.i./gal.

The currently registered product equivalent (EPA Reg. No. 3125-380) of Countdown WP, is registered for broad spectrum surface

application in/on diverse structures (food processing plants, food handling facilities, residences, schools, passenger vehicles, etc.). The currently registered product equivalents (EPA Reg. No(s). 3125-356 and 3125-372) of Countdown EC are registered for use on ornamentals and as a broad spectrum surface treatment insecticide on numerous indoor and outdoor structures in/on diverse buildings and structures (bakeries, food manufacturing and processing plants, meat, poultry and egg processing plants, schools, apartment buildings, passenger vehicles, etc.).

Tolerances

Tolerances, to support treatment of livestock feed items, are established in 40 CFR 180.436 for residues of cyfluthrin in or on fat, meat and meat by-products of cattle and horses at 0.05 ppm and in milk at 0.01 ppm. A request for cyfluthrin tolerances, to support direct dermal treatment of cattle with Bayocide® Pour-On Insecticide, of 0.4 ppm for cattle meat, fat and meat by-products and 0.08 ppm for milk is pending (EPA File Symbol 11556-RTN). Food additive tolerances are established in 40 CFR 185.1250 for residues of cyfluthrin in/on processed foods (in food handling facilities) at 0.05 ppm, tomato products at 0.5 ppm (temporary) and cottonseed oil at 2.0 ppm. Feed additive tolerances are established at 40 CFR 186.1250 for residues in/on feed commodities (in feed-handling facilities) at 0.05 ppm, cottonseed hulls at 2.0 ppm, tomato pomace at 2.0 ppm (temporary) and tomato pomace (dry) at 5.0 ppm (temporary).

Proposed Use

The proposed use of Countdown WP and WP in Packets Premise Insecticide (Reg. No(s). 3125-RRR and -PRG) is for surface applications in and around cattle and horse premises, on feedlots, to soil in 5-10 ft. bands near buildings, etc. with hand pressurized or power operated sprayers (pressure not to exceed 50 psi). Countdown WP is added to water to make a solution which contains (0.05-0.10% a.i.). **Restrictions** include: Do not apply as a space spray. Avoid direct application to exposed feed and water. The proposed use of Countdown EC Premise Insecticide (Reg. No. 3125-RRE) is for surface applications in and around cattle and horse premises, with hand pressurized or power operated sprayers (pressure not to exceed 50 psi). Countdown EC (2 lbs. a.i./gallon) is added to water to make a dilute solution of not more than 16 ml of product per gal. (0.1% a.i./gallon) before surface applications. **Restrictions** include: Do not apply as a space spray. Avoid direct application to exposed feed and water.

The proposed labels state that animals may be present during application.

Residue Data

No residue data were provided with this submission. Instead the petitioner cited data previously submitted in connection with a tolerance petition to support direct (Bayocide® Pour-On Insecticide) treatment of cattle (See S. Hummel Memorandum, 11/26/90).

The proposed use of Countdown EC(WP) Premise Insecticide is not for the direct spraying of livestock, however, they may be present at the time of treatment of the premise. Therefore, residues resulting from inadvertent exposure are discussed. The registrant states that potential exposure is minimized by applying the spray mixture directly to surfaces and not as a space spray which is specifically prohibited in the labeled use. The registrant also states that inhalation exposure will be negligible, because spray equipment will consist of low pressure systems (<50 psi) using a fan or variable pattern type nozzle.

CB-II accepts that inhalation of cyfluthrin will be negligible, the vapor pressure of cyfluthrin is only 3.3×10^{-8} mmHg at 20°C (a boiling point is not available because it decomposes before boiling).

The petitioner also claims that oral ingestion will be negligible, since only structural surfaces are to be treated. They claim that even if occasional licking of a treated surface occurred, the amount of cyfluthrin ingested would not be significant. According to the Use Directions, the maximum amount of product applied per 1,000 ft² is 16 ml for the EC formulation and 19 grams for the WP formulation. The maximum concentration of cyfluthrin on any structural surface would be 3.84 mg/ft² (16 ml X 239.9 mg/ml/1,000 ft²) and 3.8 mg/ft² for the EC and WP formulations, respectively. If a cow licked clean a 5 ft² area of surface sprayed at the maximum use rate the exposure would be 19.2 mg (equivalent to 1.3 ppm based on an assumed 15kg/feed/day) or less than 10% of the dermal exposure (dermal exposure is calculated in the following paragraph).

| Feeding level in ppm | Residue in Fat (ppm) | Residue in Muscle (ppm) | Residue in Kidney (ppm) | Residue in Liver (ppm) | Residue in Milk (ppm) |
|----------------------|----------------------|-------------------------|-------------------------|------------------------|-----------------------|
| 4.5 | 0.30 | <0.01 | NA | NA | 0.02 |
| 13 | 0.73 | 0.02 | <0.01 | <0.01 | 0.08 |
| 41 | 3.00 | 0.03 | 0.18 | 0.14 | 0.26 |

Table 1. Maximum residue levels of Cyfluthrin in Ruminants (Three dairy cattle were feed cyfluthrin for 28 consecutive days).

Inspection of the data reveals a very linear dose-response relationship; and because of this, CB-II will extrapolate likely residues at the 1.3 ppm feeding level by using the 4.5 feeding level residues.

The calculated residue estimate would then be 0.08 ppm for fat, and <0.01 for muscle, kidney, liver and milk. This would exceed the existing tolerance of 0.05 ppm for cyfluthrin residues in or on fat, meat and meat by-products of cattle and horses.

Therefore, CB-II cannot accept the argument that oral exposure can be ignored in a premise treatment (data submitted to CB concerning fenvalerate (See Richard Loranger Memorandum, 11/28/84) indicated that oral ingestion from licking and grooming to be a major source of exposure from dermal applications). However, tissue residues resulting from direct dermal application would also have occurred due to the licking/grooming behavior in cattle. Therefore, CB-II concludes that residue levels resulting from the dermal trials would take into account oral exposure because the animals were not restrained.

The petitioner states that dermal exposure can occur under two separate situations:

- 1) Inadvertent spraying of animals due to unexpected movement or droplets falling from a ceiling if the point of runoff was exceeded; and,
- 2) Animals rubbing against a treated surface.

For both exposure routes, the petitioner claims that the level of residues in tissue and milk would be negligible, since penetration would be minimal due to the protection offered by the cows hair and hide.

Having argued that the dermal route of exposure is the major exposure route, the petitioner next calculates the maximum possible exposure based on proposed use rates and also on empirically derived formulas.

The petitioner estimates the dermal exposure to livestock (cattle) from premise treatments multiplying the amount of a.i. applied per square foot, by the hide area of a typical cow.

The maximum amount of cyfluthrin a.i. applied per square foot is calculated as follows:

EC formulation:

$$(16 \text{ ml} \times 239.9 \text{ mg/ml}) / 1,000 \text{ ft}^2 = 3.84 \text{ mg a.i./ft}^2$$

WP formulation:

$$19 \text{ grams} \times 20\% \times 1,000 \text{ mg/g} = 3.8 \text{ mg a.i./ft}^2$$

The petitioner then assumes that the Insecticide diluted spray mixture is sprayed directly (and uniformly) on a bovine animal weighing 400 kg (880 lbs.). The total amount of cyfluthrin applied is calculated using the concentration of the spray mixture and the total surface area of the animal.

The surface area of cattle have been experimentally determined to be correlated with the weight of the animal according to the following relationship:

$$K = \frac{\text{area}^2 \text{ (cm)}}{\text{weight}^{2/3} \text{ (grams)}}$$

where: k - is a constant;
 area - is the measured surface area; and,
 weight - is the weight of the animal.

For Hereford cattle the average value for k is 9.4. Assuming a 400 kg animal the calculated surface area using this formula is 51,000 cm² or 54.9 ft². Then assuming that the entire surface area of the animal is sprayed, the total amount of cyfluthrin applied would be 211.2 mg (55 ft² X 3.84 mg/ft²). This is equivalent to a dermal dose of 0.53 mg a.i./kg (body weight).

The petitioner states that the maximum exposure to animals during treatment of premises would actually be much less than would be expected from direct treatment of the entire animal. The petitioner assumes that a maximum of 10% of the cows surface area will be exposed. No justification or rationale was provided to substantiate this estimate, however it seems to be a reasonable assumption for two reasons: 1) A registration for dermal treatment is being sought; and, 2) the relative low pressure of the application devices (<50 psi) would require the applicator to be fairly close to the area being sprayed thus minimizing the possibility of inadvertent spraying of the animals. The petitioner therefore estimate a dermal exposure of 0.053 mg/kg (body weight) to livestock (cattle/horses) to result from the proposes premise treatment.

Magnitude of the Residue - Dermal Application

Tissue residue following dermal application of cyfluthrin are discussed in Mobay Report No. 74050, "Depletion of Cyfluthrin Residues in Bovine Tissue and Milk from a Pour-On Formulation.", Experiment No. TR 89A-032, 6/15/90.

In the residue trials a 1% cyfluthrin formulation was applied dermally, along the backline, to six lactating Holstein cows at the rate of 0.63 or 0.9 mg a.i./kg body weight (ca 10X the estimated exposure from premise treatment based on 10% of the cows surface area being exposed). The cows ranged in size from 391 to 585 kg. The cattle received either a single dose at 0.63 mg/kg body weight followed by an additional application 12 days

later or three doses of 0.9 mg/kg body weight on consecutive days, followed by two additional doses at 14 day intervals. Samples of milk and whole blood were collected daily for seven days after a single dose (at 0.63 mg/kg body weight) and for eight days after the third dose (at 0.9 mg/kg body weight). Milk samples were not collected after the fourth and fifth doses. Residues in all blood samples were non-detectable (<0.001 ppm cyfluthrin). Table 1 below summarizes the data for the 0.63 mg/kg body weight dosing. The residue data reflect 1.2X the maximum dose, assuming 100% of the cattle's skin were exposed to the premise treatment spray. The 0.9 mg/kg data will not be discussed because the 0.63 mg/kg is more representative of the proposed use.

| Interval after Last Dose (days) | Average Residue in Whole Milk (ppm cyfluthrin) |
|---------------------------------|--|
| 0.3 | 0.002 |
| 1 | 0.007 |
| 2 | 0.009 |
| 3 | 0.015 |
| 4 | 0.009 |
| 5 | 0.005 |
| 6 | 0.004 |
| 7 | 0.004 |

Table 1. Cyfluthrin residues in whole milk after one dose of Cyfluthrin 1% Pour-On Formulation at 0.63 mg a.i./kg body weight/day.

| Tissue | Residues detected in Animal #1 (ppm) | Residues detected in Animal #2 (ppm) | Residues detected in Animal #3 (ppm) |
|--------|--------------------------------------|--------------------------------------|--------------------------------------|
| Liver | <0.002 | <0.002 | <0.002 |
| Kidney | 0.012 | 0.011 | 0.013 |
| Muscle | 0.006 | 0.008 | 0.009 |
| Fat | 0.087 | 0.072 | 0.11 |

Table 2. Cyfluthrin residues in Bovine Tissues following two dermal treatments at 0.63 mg a.i./kg body weight/day.

The residue data clearly indicate that the currently established tolerances for cyfluthrin in milk at 0.01 ppm and fat (cattle and horses) at 0.05 ppm would be exceeded by the proposed Pour-On

use. In fact, Susan Hummel in her review (EPA File Symbol 11556-RTN, 11/26/90) concluded that residues would exceed the currently established tolerances for milk (0.01) and for meat, fat, and meat byproducts (0.05 ppm) as a result of applications conducted at less than the maximum proposed use rate. In that review S. Hummel recommended that higher tolerances be proposed.

The conclusion that residues resulting from direct dermal treatment of cattle (i.e., the Pour-On) will exceed existing tolerances is further substantiated by Mobay Report No. 74051, "Cyfluthrin - Magnitude of the Residues of Cyfluthrin for Bovine Tissues Following Dermal Application of a Pour-On Formulation to Beef Cattle." (MRID No. 415557-03).

In these residue trials a 1% cyfluthrin formulation was applied dermally, along the backline, to ten Hereford, Angus, and mixed breed beef cattle at a dose of 0.44 mg a.i./kg body weight (ca 8X the estimated exposure from premise treatment based on 10% of the cows surface area being exposed). Three groups of three cattle each received 1, 2, or 3 applications with 21 days between applications. Tissue samples were collected three days after the last application because maximum residues were expected at that time (based on the results of the first residue trials).

| Tissue | Residues detected in Animal #1 (ppm) | Residues detected in Animal #2 (ppm) | Residues detected in Animal #3 (ppm) |
|--------|--------------------------------------|--------------------------------------|--------------------------------------|
| Liver | <0.002 | <0.002 | <0.002 |
| Kidney | 0.006 | 0.005 | 0.006 |
| Muscle | 0.006 | 0.005 | 0.004 |
| Fat | 0.151 | 0.110 | 0.104 |

Table 3. Cyfluthrin residues in Bovine Tissues following two dermal treatments at 0.44 mg a.i./kg body weight/day.

The data for fat clearly indicate that existing tolerances would be exceeded by direct dermal treatment at 0.44mg/kg body weight. Tolerances must be high enough to cover both currently registered and proposed feed items as well as dermal and premise use. The residue data indicate that the existing tolerances of 0.05 ppm for meat, fat, and meat by-products and 0.01 ppm for milk are inadequate. Higher tolerances need to be proposed to cover the residues resulting from all exposure routes.

CONCLUSIONS

1. This registration request amends the existing registrations for cyfluthrin formulations as follows:
 - a. Specifies use of formulations in or around livestock (cattle and horses) premises.

- b. Provides new product names (Countdown WP or EC Premise Insecticide).
 - c. Introduces product application by farmers. Previous registrations required product application by commercial applicators.
2. Tolerances on livestock commodities must be set at a level high enough to cover all proposed uses, including: treatment of livestock feed items, direct dermal treatment of livestock, ear tags, as well as livestock premise use. The use proposed in this application should be considered in connection with the pending petition (EPA File Symbol 11556-RNT) for higher tolerances in livestock products in support of direct dermal treatment (i.e., Bayocide® Pour-On Insecticide). Residue data submitted in support of direct dermal treatment of livestock indicate that the existing cyfluthrin tolerances of 0.05 ppm for meat, fat, and meat by-products and 0.01 ppm for milk are inadequate to cover all the proposed uses.
 3. CB-II cannot determine if the premise treatment by itself would exceed the existing cyfluthrin tolerances of 0.05 ppm for meat, fat, and meat by-products and 0.01 ppm for milk. All available dermal residue trials were conducted at an exposure rate an order of magnitude higher than the estimated dermal exposure resulting from premise application.
 4. Adequate enforcement methodology for the determination of cyfluthrin residues in cattle and horses is available in Pesticide Analysis Manual (PAM) Vol. II.
 5. The analytical data referenced in this review was generated by the Mobay Agricultural Chemicals Division.

RECOMMENDATIONS

CB-II recommends against this registration of Countdown EC and WP Premise Insecticide for the reason cited in Conclusions 2 and 3.

CC: R.F.; CYFLUTHRIN S.F.; Amended Use File; Circu;
E. Saito (SACB); PIB/FOD (C. Furlow).
RDI: FS; 5/29/91; EZ; 5/29/91
H7509C: DMM; dmm; CM#2; Rm800D; 557-0934; 5/29/91