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

OCT 7 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP No. 3F4266. Chlorpyrifos on Alfalfa. Request for Increased Tolerances. D195526. CB No. 12624. MRID Nos. 429175-00, -01, -02.

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THRU: Richard A. Loranger, PhD, Acting Branch Chief
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TO: Dennis Edwards/Carl Andreasen
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Registration Division (7505C)

DowElanco is proposing to increase tolerances for chlorpyrifos (O,O-diethyl O-(3,5,6-trichloro-2-pyridyl)phosphorothioate) from 3 to 8 ppm on alfalfa forage, and from 13 to 25 ppm on alfalfa hay in the subject petition. The petitioner is seeking to modify the present use by shortening the PHI when a higher application rate is used.

Tolerances for chlorpyrifos have been established on several raw agricultural commodities ranging from 0.01 to 13 ppm, and are listed in 40 CFR 180.342. Food and feed additive tolerances have also been established, and are listed in 40 CFR 185.1000 and 40 CFR 186.1000, respectively.

Chlorpyrifos is an organophosphate insecticide, and is a list A chemical. The product chemistry and residue chemistry chapters for the Chlorpyrifos RED were recently completed by CBRS (see 9/15/94 memo of S. Knizner; D198040, D203769).

Conclusions

1. All product chemistry data requirements for Lorsban 4E-HF have been met.

2. The label for the modified use of Lorsban 4E-HF on alfalfa adequately describes the proposed use.

3. The nature of the residue of chlorpyrifos in plants and animals is adequately understood. The residue to be regulated is chlorpyrifos parent.

4. Analytical methodology is available for the determination of chlorpyrifos in plant and animal commodities. These gas chromatography methods are described in PAM II, with limits of detection at 0.01 ppm. Chlorpyrifos is also completely recovered (>80%) using FDA multiresidue method protocol D, and is partially recovered (50-80%) using multiresidue method protocol E.

5. The residue field trial data are minimally adequate to support this modified use of chlorpyrifos on alfalfa since 4 of the 7 trials were conducted in the major region where alfalfa is grown, and trials were conducted at different times (5 years apart). The residue data indicate that residue levels in alfalfa forage and hay are not likely to exceed the respective 8 and 25 ppm tolerances when chlorpyrifos is used as directed (minimum 7 day PHI for rates $\leq$0.5 lb ai/A). The residue data also supports the previous conclusion that chlorpyrifos residue levels decline as the PHI increases. Note that the previous tolerances were adequate for a 21 day PHI when rates are >0.5 lb ai/A, and are supported by residue data previously submitted (see 9/15/94 RED Chapter, page 14).

   Processing study data for alfalfa meal are not required since data previously reviewed indicate that residues of chlorpyrifos do not concentrate upon processing (see 9/15/94 RED chapter, page 10).

6. The existing tolerances for cattle meat, meat byproducts and fat are adequate to cover potential residues resulting from the increased tolerances on alfalfa hay and forage. The tolerances for sheep and horse commodities are also adequate. Alfalfa is not a feed item for poultry or finishing swine, therefore the adequacy of tolerances for these animal commodities is not an issue.

7. The present tolerance of 0.25 ppm milk fat (reflecting 0.01 ppm in whole milk) may be inadequate as a result of the increased dietary burden of dairy cattle. The petitioner should propose a tolerance of 0.5 ppm (reflecting 0.02 ppm in whole milk) in a revised Section F.

Recommendations

CBTS recommends against the establishment of chlorpyrifos

2

tolerances on alfalfa forage and hay at 8 and 25 ppm, respectively, for the reason stated in conclusion 7 above.

Detailed Considerations

Product Chemistry
(refer to 9/15/94 RED Chapter)

The manufacturing process for technical grade chlorpyrifos has been adequately described, and all data requirements have been met. There are no impurities present in the technical grade product which are expected to cause residue concerns.

Lorsban 4E-HF is proposed for use on alfalfa (EPA Reg No. 62719-220), which contains 4 lb ai/gal of end use product. All of the inerts have been cleared for use.

Proposed Use

Lorsban 4E-HF is to be applied as a foliar spray using aerial or ground equipment. Application rates range from 0.25 to 1 qts/A (0.25 lb ai/A to 1 lb ai/A), depending on the pest and its pressure. A spray volume of 2 to 5 gallons of water per acre is recommended for aerial application, and a minimum of 20 gallons of water per acre is recommended for ground application. Lorsban 4E-HF may also be applied through sprinkle irrigation systems after emergence of crop. Alfalfa is not to be cut or grazed within 7 days after application of 0.5 qt Lorsban 4E-HF/A ($\leq$0.5 lb ai/A) or within 21 days after application of rates above 0.5 qt/A (>0.5 lb ai/A). A maximum of 4 applications per year, one application per crop cutting, is specified.

The present label for Lorsban 4E restricts usage to no more than 1 qt/A (1.0 lb ai/A) per application for a maximum of four applications per year, and only one application per crop cutting. The post-harvest interval restricts cutting or grazing treated alfalfa to within 7, 14, and 21 days after the application of 0.25, 0.5, and 1 qt/A of Lorsban 4E, respectively. This use is adequately supported by residue chemistry data already reviewed (see 9/15/94 RED chapter).

Plant and Animal Metabolism of Chlorpyrifos
(refer to 9/15/94 RED Chapter)

The qualitative nature of the residue in plants is considered to be adequately understood, based on acceptable radiolabeled studies in corn (cereal grain group) and sugar beets (tuber vegetable group) where chlorpyrifos was applied at rates of 1 to 1.5 lb ai/A. These

studies were supplemented by data from studies on apples, dry beans, and soybeans. Chlorpyrifos is extensively metabolized to several components in plants, none of which are of toxicological concern. The regulated terminal residue in plants is chlorpyrifos.

The qualitative nature of the residue in ruminants is also adequately understood, based on acceptable radiolabeled studies on goats where chlorpyrifos was fed to the animals at levels of 5 to 21 ppm. Radioactive residues were adequately characterized in milk and all edible commodities. Chlorpyrifos is extensively metabolized to several components in ruminants, none of which are of toxicological concern. The regulated terminal residue in animal commodities is chlorpyrifos.

The metabolism of chlorpyrifos in poultry is irrelevant to this petition since alfalfa is not a poultry feed item. Rotational crop data requirements are also irrelevant to this petition since alfalfa is not a rotational crop.

Enforcement Methodology
(refer to 9/15/94 RED Chapter)

Analytical methodology is available for the determination of chlorpyrifos in plant and animal commodities. These gas chromatography methods are described in PAM II, with limits of detection at 0.01 ppm. Chlorpyrifos is also completely recovered (>80%) using FDA multiresidue method protocol D, and is partially recovered (50-80%) using multiresidue method protocol E.

Residue Data
(MRID No. 42917501)

The petitioner has submitted new residue data from field trials conducted in California (1), Illinois (1), New York (1), and Wisconsin (1) during 1991. Lorsban 4E was applied using ground application equipment at all sites except the one in California, where application was with aerial equipment. One spray application at a rate of 0.5 or 1 qt/A (0.5 or 1.0 lb ai/A) per cutting was applied to a total of four cuttings. An exception was to the second application in Wisconsin, where 0.45 and 0.9 qt/A was applied instead of 0.5 and 1 qt/A seven days before harvest. Samples of alfalfa were collected from the fourth cutting 7 days after the last application at a rate of 0.5 lb ai/A, and 7 and 14 days from the last application at the rate of 1.0 lb ai/A. The alfalfa was harvested by hand or cut using commercial cutter/swathers. The green forage was randomly collected, placed in polyethylene lined cotton bags and immediately frozen. The cured hay was randomly sampled from windrows 3 to 12 days after cutting, or by sampling from green forage that had been dried in drying sheds for 3 days. Four replicates per plot were sampled,

and stored frozen until analyzed. All samples were analyzed within a 5 month period. Storage stability data previously reviewed indicates that chlorpyrifos is stable in alfalfa forage and hay for at least 12 months (see 9/15/94 RED chapter, D198040, 203769). Storage stability data on other commodities indicates that chlorpyrifos is stable for over 4 years (see 2/29/84 Registration Standard).

Residues of chlorpyrifos were determined using GC method ACR 84.4.S3. Chlorpyrifos is extracted with acetone, and cleaned up using a C18 column. Quantification was by GC using a flame photometric detector. When control samples were fortified at levels of 0.01 to 50 ppm of chlorpyrifos, average recoveries ranged from 84 to 89% for alfalfa green forage and hay, respectively. A variation of this method has been reviewed by residue chemistry branch and found adequate for data collection purposes (see 10/14/88 Chlorpyrifos SRR).

The petitioner also referenced field trial data previously submitted in support of a label amendment for Lorsban 4E (MRID No. 41937401). In one experiment conducted in 1984, alfalfa plots in California (1), Illinois (1) and Michigan (1) were treated with a single application of 0.5 qt of Lorsban 4E/A (0.5 lb ai/A) seven days before each cutting, for a total of four cuttings during the season. Samples of green forage and cured hay collected seven days after the application to the fourth cutting were analyzed for residues of chlorpyrifos. Fresh green forage was cut and dried in the field for 14 days in California, 10 days in Illinois, and in a greenhouse in Michigan for 7 days to obtain 1 to 1.5 lb samples of cured hay. Samples were stored frozen for no more than 4 months prior to analysis.

Residues of chlorpyrifos were determined using method ACR 78.10, which involves extraction of residues with acetone, and analysis by gas chromatography using a flame photometric detector[1]. The efficiency of the method was determined by fortifying control samples at levels of 0.5 to 100 ppm. Recoveries averaged 97 to 100% for green forage and hay, respectively, over this range.

A summary of the residue data submitted in both reports is provided in the table that follows.

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[1]Samples were also analyzed for the TCP metabolite, but since this metabolite is no longer included in the tolerance expression results will not be discussed here. Chlorpyrifos and TCP were determined using two different GC methods.

TABLE I. SUMMARY OF RESIDUE DATA CONSIDERED FOR AMENDED USE OF CHLORPYRIFOS ON ALFALFA

LOCATION	RESIDUE RANGE (ppm) 0.5 lb ai/A, 7 day PHI	RESIDUE RANGE (ppm) 1.0 lb ai/A, 7 day PHI	RESIDUE RANGE (ppm) 1.0 lb ai/A, 14 day PHI
Forage, 1989			
Corning, CA*	0.58 - 1.2	1.7 - 5.1	0.25 - 0.37
Geneseo, IL	1.8 - 2.6	5.2 - 6.8	2.0 - 2.7
Phelps, NY	4.0 - 4.8	13 - 16	9.1 - 9.8
Verona, WS	5.9 - 6.4	8 - 16	3.1 - 7.1
Forage, 1984			
Davis, CA	2.0 - 2.5		
Atkinson, IL	0.75 - 0.98		
Saginaw, MI	1.8 - 2.3		
Hay, 1989			
Corning, CA*	2.1 - 2.9	3.5 - 5.8	1.3 - 2.5
Geneseo, IL	6.3 - 9.4	21 - 29	9.8 - 11
Phelps, NY	17 - 19	28 - 37	24 - 34
Verona, WS	15 - 21	27 - 58	5.7 - 19
Hay, 1984			
Davis, CA	4.5 - 6.0		
Atkinson, IL	1.6 - 2.4		
Saginaw, MI	5.9 - 6.7		

* Aerial Application

It is concluded that the residue field trial data are minimally adequate to support this modified use of chlorpyrifos on alfalfa since 4 of the 7 trials were conducted in the major region where alfalfa is grown, and trials were conducted at different times (5 years apart)[2]. The residue data indicate that residue levels in

[2]Note that our recent document entitled, Pesticide Reregistration Rejection Rate Analysis: Followup Guidance-Number and Location of Domestic Crop Field Trials, requires 9 trials for alfalfa, and was considered in determining the adequacy of data. This requirement is applicable to field trials conducted in 1995 or later (this petition was submitted in 1993). Also, since alfalfa is not directly consumed, additional data is less critical.

alfalfa forage and hay are not likely to exceed the respective 8 and 25 ppm tolerances when chlorpyrifos is used as directed (minimum 7 day PHI for rates ≤0.5 lb ai/A). The residue data also supports the previous conclusion that residue levels decline as the PHI increases. Note that the previous tolerances were adequate for a 21 day PHI when rates are >0.5 lb ai/A, and are supported by residue data previously submitted (see 9/15/94 RED Chapter, page 14).

Processing study data for alfalfa meal are not required since data previously reviewed indicate that residues of chlorpyrifos do not concentrate upon processing (see 9/15/94 RED chapter, page 10).

Secondary Residues in Meat and Milk

Chlorpyrifos tolerances of 0.05, 0.05, 0.3, 0.25, and 0.01 ppm have been established for cattle meat, meat byproducts, fat, milkfat, and whole milk, respectively, in 40 CFR 180.342. These tolerances have been confirmed to be appropriate levels resulting from dietary intake and eartag uses in the 9/15/94 Chlorpyrifos RED Chapter.[3] The tolerances for meat, meat byproducts, fat and whole milk are based on data from cattle feeding studies where animals were fed up to 10 ppm chlorpyrifos. The milkfat tolerance was extrapolated from the 0.01 ppm tolerance for whole milk (for details see 11/21/83 memo of K. Arne, FAP No. 1H5295 and Chlorpyrifos Registration Standard dated 2/29/84).

A theoretical diet for beef cattle containing a probable combination of feed items with chlorpyrifos residues might consist of 25% alfalfa hay, 40% apple pomace, and 35% soybean meal (see also D. Edwards memo dated 3/21/89). These feed items contain 89%, 40%, and 92% dry matter, respectively. The dietary burden therefore would be 9.1 ppm.[4] The existing tolerances for cattle meat, meat byproducts and fat are therefore adequate to cover potential residues resulting from the increased tolerances on alfalfa hay and forage. The dietary burden of sheep and horses may be estimated similarly, and therefore the presently established tolerances are also adequate. Alfalfa is not a feed item for poultry or finishing swine, therefore the adequacy of tolerances for these animal

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[3]It was recommended however, that the whole milk tolerance be revoked and the milk fat tolerance be revised to include the statement "reflecting 0.01 ppm in whole milk".

[4]Dietary burden (ppm) = $\sum$ (%diet/ %DM) x tolerance (ppm). See Pesticide Reregistration Rejection Rate Analysis Residue Chemistry, Follow-up Guidance for Calculating Livestock Dietary Exposure, Updated Livestock Feeds Tables, June 1994, NTIS, EPA 738-K-94-001. Note also that the tolerances used for apple pomace and soybean meal in the theoretical diet were 2 ppm and 0.3 ppm, respectively, as recommended in the 9/15/94 RED Chapter.

7

commodities is not an issue.

A theoretical diet for dairy cattle containing a probable combination of feed items with chlorpyrifos residues might consist of 70% alfalfa hay and 30% apple pomace. The dietary burden therefore would be 21.2 ppm. Feeding study data from cattle fed at 26 to 30 ppm indicated that residue levels in milk were 0.02 to 0.03 ppm (see 2/29/84 Registration Standard). Since the dietary burden of dairy cattle may approach these levels as a result of the higher residues on alfalfa hay, it is suggested that the petitioner propose a tolerance of 0.5 ppm for milk fat (reflecting 0.02 ppm in whole milk).

cc: RF, PP No. 3F4266, S. Willett, E. Haeberer, Circ, PIB/FOD (C. Furlow)
CM2:305-6380:RM804C:7509C:SHWillett:shw-10/4/94
RDI: E. Haeberer, 10/5/94; R. Loranger, 10/5/94

8