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

JUL 25 1994

July 25, 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 241-337. PROWL 3.3 EC Herbicide. Amended use of pendimethalin (ANSI) on sugarcane in Hawaii. Submission dated 7/22/93. CBTS No. 112300. DP Barcode D193627. PC Code 108501.

FROM: R. W. Cook, Chemist *RW Cook*
Tolerance Petition Section I
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

THRU: Richard Loranger, Ph.D., Acting Chief *R. Loranger*
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

TO: R. J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (7505C)

We have previously considered tolerances of 0.1 ppm (see reviews PP2F2765, 1/14/83, 9/21/83, 11/26/90, and 2/11/93, R. W. Cook) for residues of pendimethalin and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol in or on sugarcane in Texas and Louisiana only. A favorable recommendation was given, provided that the label bear a restriction against the use of sugarcane forage as an animal feed. The tolerance was established on 2/25/93 under 40 CFR 180.361. The associated registration bears the limitation "Do Not Use In Hawaii", based upon the absence of residue data from field trials conducted in Hawaii. The petitioner now wishes to remove the geographical restriction, by presenting field trials residue data from Hawaii.

Conclusions:

1. The metabolism of pendimethalin in plants is not adequately known for purposes of establishing additional tolerances.

For the purposes of this amended use request, the nature of the residue in sugarcane is adequately known. The residue of concern is the parent compound pendimethalin and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol.



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2. For the purposes of the proposed amended use, we conclude that animal metabolism is adequately understood. The residue of concern is the parent compound pendimethalin and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol.
3. Analytical methodology is available for enforcement purposes. The methods available include M-1212, M-1208, M-1207 in PP3F2765 for the parent compound and PAM methods II and IV for the metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol (CL 202347).
4. Combined residues of pendimethalin and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol are not likely to exceed 0.1 ppm in treated sugarcane.
5. Since detectable residues of pendimethalin and its metabolite are not expected in livestock feed items, no residues of pendimethalin and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol are likely to occur in meat and milk. We have extended this conclusion to poultry and eggs, since molasses is not a poultry feed item.

Recommendations:

We recommend, TOX considerations permitting, for the amended use of pendimethalin on sugarcane in Hawaii.

We note that the recent "EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances", June 1994, when effective in 1995, indicates that a minimum of 8 acceptable field trials and a minimum of 16 samples are required for consideration of tolerances for the commodity sugarcane. Each composite sample (minimum of two samples per location) should be collected by a separate run through the treated plot. Multiple analyses of a single sample or of subsamples constitute the equivalent of only one data point. Additional formulations would require additional residue data. Other requirements may also apply

In this case, we do not believe there is a need for additional residue data because radiotracer data have shown little radioactivity in sugarcane and because field residue data shows no detectable residues of <0.005 ppm in treated sugarcane.

Detailed Considerations

Directions for Use:

PROWL HERBICIDE 3.3 EC: EPA Reg No. 241-337 For Use In Sugarcane Grown In Hawaii.

PROWL 3.3 EC may be applied twice per season, preemergence through layby, in plant or ratoon sugarcane.

Apply 4.8 to 9.7 pints (2.0 lbs. a.i. to 4.0 lbs. a.i) per acre of PROWL 3.3 EC but do not exceed 14.4 pints (6.0 lbs. a.i.) per acre in one growing season.

For broadcast application, apply PROWL 3.3 EC in 10 or more gallons of water or in 20 or more gallons of liquid fertilizer per acre. For aerial application, apply in 5 or more gallons of water per acre. Do not make aerial applications at close-in because complete and uniform coverage cannot be obtained.

Do not apply more than 14.4 pints per acre of PROWL 3.3 EC during one growing season.

In a recent action, additional changes to the PROWL 3.3 EC label have been proposed, primarily removing the limitation to two applications per growing season and the addition of another application in late summer or early fall. The proposed supplemental labeling still bears the previously approved restriction "Do not use in Hawaii". This proposed change is currently in reject status, pending inclusion of a 90 day PHI and other minor label changes (see G. F. Kramer review of EPA Reg. No. 241-337, 1/7/94.)

Nature of the Residue in Plants and Animals:

No plant metabolism data are presented in this amended use proposal.

The nature of the residue in plants has been previously discussed in our review of PP2F2765 (1/14/83).

Recently, questions regarding the nature of the residue in plants have been raised in regard to potatoes since ¹⁴C residues in mature potatoes were not conclusively identified/characterized. Additional metabolism study on potatoes at a higher initial dosage level was required.

We conclude that for the purposes of the amended use, the nature of the residue in sugarcane is adequately understood. The residues of concern are pendimethalin (N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzeneamine) and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol.

Nature of the Residue in Animals:

No animal metabolism data are presented in this amended use proposal.

Animal (goat and cattle) feeding studies have been conducted in connection with PP5F1556 (pendimethalin on corn and cottonseed, A. Smith, 5-5-75). An additional goat metabolism study submitted under PP3F2788 (wheat and barley) was reviewed by F. Griffith, 3/5/91 and 4/29/92; the goat metabolism study does not define the nature of the residue in ruminants.

A revision entitled " Table II (June 1994)" has removed sugarcane forage as a raw agricultural commodity and sugarcane forage and bagasse as livestock feed items. The only livestock feed item resulting from the production of sugarcane is molasses. Molasses is no longer considered a poultry feed item. Based upon the low level (10%) of molasses in the cattle diet and pending resolution of the above cited goat metabolism study, we conclude that animal metabolism is adequately understood for the purposes of the proposed amended use. The residue of concern is the parent compound pendimethalin and its metabolite 4-[(1-ethylpropyl)-amino]-2-methyl-3,5-dinitrobenzyl alcohol.

Analytical Method:

The analytical method used for the analysis of sugarcane is:
MRID 423859202:

PROWL (CL 92,553) and Alcohol Plant Metabolite (CL 202,347): Validation of GC Method M 2140 for the Determination of CL 92,553 and CL 202,347 in Sugar Cane and Sugar Cane Forage." by B. Reliford, 1/14/93, American Cyanamid Company.

In addition, the registrant submitted:

MRID 42859203: [Not Reviewed]

CL 92,553 (pendimethalin): Independent Laboratory Validation of GC Method M1930 for the Determination of CL 92,553 and CL 202,347 Residues in Alfalfa. by R. Sisco, 11/5/90.

and

MRID 42859204: [Not Reviewed]

CL 92,553 (pendimethalin): Validation of Method M2243 for the Determination of CL 92,553 and CL 202,347 Residues in Canola Forage, Hay, and Seed at ChemAnalysis, Inc. by S. Witkonton, 12/30/92.

Since we are interested here in the amended use for pendimethalin on Hawaiian sugarcane, we have not reviewed MRID 42859203 or MRID 42859204 (the methods for alfalfa, canola forage, hay, or seed). These submissions will be reviewed at such time as a petition for

use on alfalfa or canola are submitted.

The method described in MRID 423859202 uses methanol:water extraction solvent and the residue is partitioned into hexane. Following cleanup on a GPC column, the eluates for CL 92,553 and CL 202,347 are further cleaned by solid phase extraction cartridge with Florisil eluted with ethyl acetate:hexane solutions. The residues are quantitated by electron capture gas chromatography with a Ni⁶³ detector. This method differs from the previous method by eliminating benzene.

The method sensitivity is 0.05 ppm for both CL 92,553 and CL 202,347. Recovery studies for both CL 92,553 and CL 202,347 in each commodity (sugarcane and sugarcane forage) were conducted at 3 levels of fortification (0.00 ppm, 0.05 ppm, and 2.00 ppm) 3 times over a 3 day interval. Supplemental recovery studies were conducted on sugarcane (2 sets) and sugarcane forage (1 set).

Values for apparent residues of CL 92,553 and CL 202,347 in control samples of sugar cane and sugarcane forage were <0.002 ppm. Recovery of CL 92,553 in sugarcane ranged from 64 to 84% at 0.05 ppm and 83 to 93% at 2.0 ppm. In sugarcane forage, recovery of CL 92,553 ranged from 84 to 94% at both 0.05 ppm and 2.00 ppm. Recovery of CL 202,347 in sugarcane ranged from 54 to 92% at 0.05 ppm and 95 to 117% at 2.0 ppm. In sugarcane forage, recovery of CL 92,553 ranged from 76 to 92% at 0.05 ppm and from 92 to 103 at 2.00 ppm. We note that no recoveries were performed at the established tolerance level of 0.1 ppm.

Adequate methods are available in PAM for the analysis of pendimethalin and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol. The methods available include M-1212, M-1208, M-1207 in PP3F2765 for the parent compound and PAM methods II and IV for the metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol (CL 202347).

Frozen storage studies conducted on other commodities have indicated freezer stability for intervals up to 24 months.

Magnitude of the Residue:

CL 92,553 (Pendimethalin): Residues of CL 92,553 and its metabolite CL 202347 in the cane of sugarcane grown in Hawaii after sequential application of Prowl 4EC herbicide. by T. Schaefer, 5/20/92. (MRID 42859201)

A field trial was conducted near Papaikou, on the island of Hawaii. Three plots each 18 x 20 feet (four rows of sugarcane) were treated as control, 1X and 2X. Treated plots received an

preemergence application of 3.08 lb. a.i./A (1X) or 6.28 lb. a.i./A (2X) on May 16, 1990. Rainfall (0.5 inch) within one day after application served to incorporate the treatment. After the preemergence application on 5/16/90, a second late postemergence application was made 8/1/90. Rainfall (0.5 inch) within three days after late postemergence application incorporated the treatment. Routine fertilization by aerial and broadcast equipment occurred during April, 1990, to March 1991. Additionally, diuron (KARMEX™; 3.2 lbs. a.i./A.) was applied May 30, 1990 by handheld broadcast equipment and diuron (KARMEX™; 3.0 lbs. a.i./A.) + ametryne (EVIK™; 3.0 lbs. a.i./A.) applied by aerial application June 28, 1990.

Sugarcane samples were obtained at the earliest normal interval, 8/1/91. In brief, 12 plants from the inner two rows were stripped of foliage and chopped into three segments, carried out of plot, and rechopped into two to six inch segments. These smaller segments were then composited into one sample, taking care to include segments from the entire plant. Samples were frozen within one hour of sampling. The samples remained in frozen storage about four months prior to analysis. No supporting storage stability data were provided.

The one control sample from one plot in Hawaii contained less than 0.002 and <0.001 ppm of pendimethalin (CL 92,553) and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol (CL 202,347), respectively.

The one treated sample from one plot in Hawaii reflecting 1X application of 3.0 lbs. a.i./A. preemergence and 3.0 lbs. a.i./A. late postemergence of PROWL 4EC contained less than 0.005 ppm each of pendimethalin (CL 92,553) and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol (CL 202,347).

The one treated sample from one plot in Hawaii reflecting 2X application of 6.0 lbs. a.i./A. preemergence and 6.0 lbs. a.i./A. late postemergence of PROWL 4EC contained less than 0.005 ppm each of pendimethalin (CL 92,553) and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol (CL 202,347).

We note that the residue data reflect application of the PROWL 4EC formulation, whereas the current action is for the 3.3 EC formulation of pendimethalin.

Based upon this very limited data set, and previously reviewed pendimethalin data in PP2F2765, we conclude that combined residues of pendimethalin and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol from the amended use are not likely to exceed the established 0.1 ppm in treated sugarcane.

The changes recommended in our recent review of PROWL 3.3 EC (see

G. Kramer review of EPA Reg. No. 241-337, 1/7/94.) are not likely to result in increased residue levels in sugarcane.

We note that the recent "EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances", June 1994, indicates that a minimum of 8 acceptable field trials and a minimum of 16 samples are required for consideration of tolerances for the commodity sugarcane. Each composite sample (minimum of two samples per location) should be collected by a separate run through the treated plot. Multiple analyses of a single sample or of subsamples constitute the equivalent of only one data point. Additional formulations would require additional residue data. Other requirements may also apply

In this case, we do not believe there is a need for additional residue data because radiotracer data have shown little radioactivity in sugarcane and because field residue data shows no detectable residues of <0.005 ppm in treated sugarcane.

Meat, Milk, Poultry and Eggs.

In our previous considerations, the label restriction "Do not graze treated fields or feed treated forage or fodder to livestock" was adequate to alleviate our concerns of secondary residues in meat and milk. However, a revision entitled " Table II (June 1994)" has removed sugarcane forage as a raw agricultural commodity and sugarcane forage and bagasse as livestock feed items. The only livestock feed item resulting from the production of sugarcane is molasses, which can occur at 10% of the beef and dairy cattle diet. Molasses is no longer considered a poultry feed item.

We have previously concluded that the cattle dietary burden is significantly less from the ingestion of molasses than from corn grain and forage. Therefore, established meat and milk tolerances are adequate to cover secondary residues from the proposed use of pendimethalin on sugarcane in Hawaii. Residues of pendimethalin are not expected to occur in poultry or eggs, since sugarcane molasses is no longer considered a poultry feed item.

cc: RF, Circ. , R. Cook, PP2F2765, SF
RDI:RSQ:7/22/94:RAL:7/22/94
H7509C:CBTS:TPSI:rcook:7/5/94:Rm804H