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

DEC 3 1985

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Pendimethalin Registration Standard: Addendum #1

FROM: Charles L. Trichilo, Chief
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TO: Amy Rispin
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and

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Attached is addendum #1 to the Residue Chemistry chapter of the pendimethalin Registration Standard which was completed on 7/20/84. This addendum was produced by DYNAMAC Corporation.

The projected return date for this addendum is November 25, 1985.

This addendum provides a reply to a response to deficiencies discussed in the Residue Chemistry chapter of the pendimethalin standard submitted by American Cyanamide Company and dated 7/15/85.

This addendum contains no confidential information.

If you need additional information please advise.

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Subject File
Reading File

RDI:RBPerfetti:11/23/85:RDSchmitt:11/25/85:x 557-7484.

PENDIMETHALIN ADDENDUM #1

RESIDUE CHEMISTRY

Task 4

INTRODUCTION

American Cyanamid Co. has responded in a letter from W.A. Steller, dated June 28, 1985, regarding certain residue and metabolism data requirements set forth in the Pendimethalin Registration Standard issued by EPA. In this letter, American Cyanamid Company presents arguments regarding the necessity of the data requirements for plant metbolism, animal metabolism, processed products of various oil seed commodities, residues in fish, and residues in tobacco. No additional metabolism or residue data were submitted. Specific data requirements set forth in Table A, Generic Data Requirements for Pendimethalin, the registrant's response, and our comments and conclusions are detailed below.

Data requirements - footnotes 7 and 8: The nature of the residue in plants is not adequately understood. Additional plant metabolism data are required to reveal the complete identity of radioactive extractable and nonextractable residues encountered in plant tissue resulting from treatment with radiolabeled pendimethalin. Levels of metabolites remaining in polar fractions must be determined for possible toxicological residue conerns.

Registrant's response: The registrant contends that there is essentially no uptake of pendimethalin from soil by plants and that total ^{14}C-residues following foliar application of radiolabeled pendimethalin were insignificant and too low for total identification.

Our Comments: We have reevaluated the available plant metabolism data and find that studies with radiolabeled pendimethalin have detected total residues of >0.1 ppm, expressed as pendimethalin, from preemergence or preplant incorporated soil

2

application in lima bean, snap bean, table beet, cotton, potato, rice, and soybean plants; with the two highest levels of 0.46 ppm and 0.58 ppm occurring respectively, in rice plants harvested 140 days and potato foliage harvested 30 days after treatment. Thus, the registrant's data show the uptake of pendimethalin from soil does occur. In all of these studies much less than 50% of the total terminal residue in the tissues analyzed was identified and quantified. Summarized results of attempts at identification or quantification of residues are: (i) in corn plants 30 days after soil treatment, a chloroform partition from the plant extraction solution was found to contain 49-74% pendimethalin and 5-7%, CL 202,347; adjusting for extraction efficiency and the proportion of the extraction solution partitioned into chloroform, the percentage of the total terminal residues identified was 29-44% (MRID 00106779); (ii) in corn plants harvested two weeks after a foliar application, 67% of the total radioactivity was extractable and a total of 7% was identified as pendimethalin, CL 202,347 or as CL 217,146 (MRID 00093698); (iii) in table beets harvested approximately 210 days after application, 67% of the total radioactivity was extracted and 39% was identified as pendimethalin or CL 202,347 (MRID 00106779); (iv) in cotton plants harvested 14 days after treatment, 91% of the radioactivity was extractable and 11% was identified as pendimethalin (MRID 00046278); (v) in rice plants harvested 28-140 days after application 41-60% of the total radioactivity was extracted and apparently 60% of the extracted radioactivity was identified as pendimethalin or CL 99,900 (MRID 00067293); (vi) in peanut hulls harvested 14 weeks after application 53% of the total radioactivity was extracted and 11% was identified as pendimethalin, CL 202,347 or CL 99,900 (MRID 00051965); (vii) in peanut hulls harvested at maturity after a preplant incorporated treatment, 69% of the total radioactivity was extracted and 14% was identified as pendimethalin, CL 202,347, CL 217,146, CL 113,072, and other unspecified compounds, (Zulalian et al., 1980, Residue Report No. PD-M Vol. 16-30).

We reiterate our previous conclusions that significant fractions of the extractable and unextractable radioactive residues found in plants were not identified and again recommend that more rigorous acid, base, and/or enzymatic hydrolysis steps be included in the experimental methodology for the following reasons:

3

1) unidentified extractable radioactivity was usually associated with highly polar material, and, in some cases reaction of this polar material with diazomethane indicated the presence of pendimethalin-related compounds; and

2) mild hydrolysis with acidic methanol (2% HCl/98% methanol) used in the initial extraction step described in the majority of the submitted metabolism studies did not release a sufficient percentage of the total radioactivity present in numerous tested plants.

The petitioner must either characterize the extractable and unextractable radioactivity encountered in representative plant tissues or demonstrate unequivocally that the unextractable residues are fragmentary components derived from radiolabeled pendimethalin that have been incorporated into naturally occurring plant products.

Data requirements - footnote 9: Metabolism studies utilizing ruminants are required.

Registrant's response: The registrant contends that the ^{14}C-activity detected in tissues from goats dosed at exaggerated dose levels of 0.5 ppm (5x), 1.5 ppm (15x), and 20 ppm (200x) were relatively low and that at "normal feeding rates, residues could never be quantitatively assayed using conventional residue methodology."

Our comments: Our concern is that residues are present in liver and kidney from a goat dosed at a feeding level equivalent to 5x the maximum expected dietary intake of pendimethalin residues; these residues must be characterized.

Data requirements - footnote 24: Residues of pendimethalin and its metabolite in edible tissues of catfish and crayfish are required.

Registrant's response: The registrant contends that residues of pendimethalin in fish resulting from registered uses on soil are of no concern because they

have "shown that extremely low levels of pendimethalin occur in the water of flooded rice fields and further that the residues disappear rapidly." Thus, they state further that there is "no potential for residues of pendimethalin in any species of fish from the labeled use on rice fields."

Our comments: We have reevaluated the available fish metabolism data (I.P. Kapoor, 1974 PP#5G1567, no MRID assigned) and find that they clearly demonstrated a short-term accumulation of pendimethalin residues in the viscera and edible muscle of fish; residues peaked after about 14 days of exposure in a static, laboratory-simulated aquatic system containing soil treated with [^{14}C]pendimethalin at a rate equivalent to 2 lb ai/A.

We agree that extremely low levels of pendimethalin occur in water of flooded rice fields; the registrant has presented data that indicate maximum pendimethalin residues of 0.057 ppm may occur in water 8 days following a single postemergence, dry-seeded application of the 4 lb/gal EC formulation at 1-2 lb ai/A [PP#OF2401 (099889)] and that pendimethalin residues decline to nondetectable levels (<0.002 ppm) 42 days posttreatment. We wish to point out that total ^{14}C-residues (expressed as pendimethalin equivalents) were 2.7 ppm in edible muscle of fish after 1 day of exposure to water containing residues of [^{14}C]pendimethalin at 0.004 ppm; therefore, we do not agree that there is no potential for residues of pendimethalin in fish from use of pendimethalin on rice fields. The detection of ^{14}C-residues in fish exposed to radiolabeled material necessitates a requirement for residue studies with fish conducted, preferably under natural field conditions. As an alternative to the requested residue study using catfish and crayfish, the registrant may propose a label restriction prohibiting use of pendimethalin on rice fields also used for the production of food fish.

Data requirements - footnote 14: Depending on the results of the requested metabolism data, additional processing data may be required for oil seed commodities.

Registrant's response: The registrant protests the request to perform one additional processing study for soybeans, to provide data which will be translated

5

to all other seed crops for which such data will be required. The protest is based upon the contention that "the tolerances in corn, cottonseed, soybeans, peanuts, and sunflower seeds are negligible tolerances hence obtaining a sample with residues at or near the tolerance is impossible."

Our comments: This contention is contraindicated by a report submitted by American Cyanamid Co. (MRID 0051965) where residues of 1.65 ppm in peanut hulls, 0.16 ppm in peanut seeds, and 0.21 ppm in mature plants were detected in plants grown in soil treated with the equivalent of 0.75 lb ai/A pendimethalin (1x the maximum registered rate). Analysis of the extract from peanut hulls (which contained 53% of the total radioactivity from application of [^{14}C]pendimethalin) demonstrated that 20% of the extracted residues was either pendimethalin per se or CL 202,347. These data clearly indicate that detectable residues of these compounds may occur in the processed commodities obtained from peanuts following registered pendimethalin applications. With pendimethalin, a nonpolar compound, concentration in oil processed from seeds of crop plants seems quite possible. Therefore, we see no basis for exempting the registrant from providing at least one processed food/feed study from raw agricultural commodity samples bearing field-treated detectable residues so that concentration factors, if any, can be calculated for processed commodities.

Data requirements - footnote 27: Residue data involving the metabolism of pendimethalin in tobacco using radioisotope techniques; and residue data involving pendimethalin metabolites in or on green freshly-harvested tobacco. If residues exceed 0.1 ppm, additional data on pyrolysis products must be submitted.

Registrant's response: The registrant states that "we have submitted sufficient residue data for these uses [soil applied incorporated and layby treatments] to demonstrate that pendimethalin residues do not occur."

Our comments: The registrant did submit residue information (1983, Prowl herbicide EPA Reg. No. 241-243. Registration application for PROWL layby applications in tobacco. Report nos. C-2202 and C-2203. Accession No. 250807) indicating

that residues were <0.1 ppm (nondetectable) in or on tobacco after the registered soil or layby application. The Pesticide Assessement Guidelines (Subdivision O: Residue Chemistry, U.S. EPA, p. 33) specifically require that a residue profile for tobacco be provided which includes the active ingredient and all significant plant metabolites of the active ingredient, translocated degradation products from soil, and photodegradation products. These studies are required even if residues are less than 0.1 ppm, and should normally involve radioisotopic techniques. No studies were submitted depicting pendimethalin residues in or on tobacco following the registered use involving direct foliar application for sucker control; such use would be expected to result in much higher residues in tobacco than the registered soil and layby applications. Therefore, the data requested are still required; except that data involving pendimethalin residues of concern in or on green freshly-harvested tobacco as the result of two treatments with the 3 lb/gal EC formulations at 1.5 lb ai/A will not be required if the registrant chooses to withdraw the registered foliar use for sucker control on tobacco.