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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 241-243. Response of 5/13/91 to Agency letter of 8/25/89, presumably on: [Branch No. 5273 (K. Dockter) 7/3/89 review of adding Layby use in Cotton to **PROWL® 4E** (pendimethalin) label]. MRID 418812-01 & 02. CB 8138. D165329.

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THRU: A.R. Rathman, Section Head
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TO: R. Taylor / V. Walters, PM Team # 25
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In response to an Agency letter dated 8/25/89, American Cyanamid Company has submitted residue data to support the previously requested amended registration for the herbicide pendimethalin to allow the addition of post-directed layby applications (to the soil between rows following the last normal cultivation) in cotton. In the above cited review, we had concluded that appropriate residue field trials were required for this additional use of pendimethalin on cotton.

A validation study of GC method M-2029 for determining these residues in ginned cottonseed, as well as the current [11/90] label and the proposed supplemental labeling dated 4/29/91 were also provided.

In that review, we had stated that:

1. Detectable levels [0.06 ppm] of pendimethalin did result in pre-plant treated cotton [PP# 5F1556].

2. Other Cyanamid data showed residues of 0.46 ppm and 0.58 ppm had occurred respectively, in rice plants harvested 140 days and potato foliage harvested 30 days after preemergence or preplant incorporated

soil application [C. Trichilo 12/3/85 Addendum #1 to the Standard].

3. Over-tolerance [>0.1 ppm] pendimethalin residues may result from the proposed added post-directed layby use in cotton.

The current submission contains a study [418812-01] of the magnitude of the residue of pendimethalin after layby use in cotton conducted in 1989 field trials in California [2] and Arizona [1]. Prowl® 4EC was applied at 1.5 [or 3] lb ai/A at planting and again, at the same rates, as a directed post application to the ground below the cotton at layby 60 days prior to harvest. Samples of cotton bolls were collected, ginned, and stored frozen for 12 months prior to analysis.

Method M-2029, with two, specified modifications, was used by ChemAlysis, Inc. to determine parent compound and the metabolite, 4-((ethylpropyl)-amino)-2-methyl-3,5-dinitrobenzyl alcohol, as follows. Cottonseed samples of about 20 g were blender ground, extracted with hexane/isopropanol [75/25], partitioned into hexane, cleaned up by GPC and SPE LC-Florisil using an ethyl acetate/hexane gravity elution system, and analyzed by fused silica GC/ECD. At a method sensitivity of 0.05 ppm, residues were reported as non-detectable in all samples. Some raw data and chromatograms appear supportive, but cottonseed storage stability data were not provided. The referenced storage stability data reported in C-2695.2 [1985; MRID 40535101] has been judged unacceptable, which see Standard update of 3/19/90. Therefore, the validity of the current residue data is open to question.

We have also noted that if detectable residues are found in cottonseed, a processing study is required, which see Loranger / Perfetti 1/29/91 memorandum on: "Plant metabolism and processing study requirements for re-registration of pendimethalin".

The ChemAlysis validation study [418812-02] of the Cyanamid Method SOP M2029, as currently modified, reported recoveries of 98±6% and 80±10% for parent and metabolite, respectively. This validation was conducted at fortification levels of 0.05 ppm and 0.25 ppm for each compound. A sensitivity of 0.05 ppm for each compound was claimed. Some chromatograms of ONLY the higher spiking level, and without raw data and calculations were provided. Hence, we are not able to verify the claims made in this validation study.

Recently, the Registrant has agreed to perform all of the remaining residue chemistry studies which were discussed in the Loranger / Perfetti memorandum of 1/29/91, which see E. Zager 7/24/91 memorandum; CBRS 8118.

Conclusion and Recommendation

The validity of the current residue data is open to question, because the available storage stability data is not adequate. Appropriate storage data are required for this additional use of pendimethalin on cotton.

Therefore, we continue to recommend against the proposed amended registration of **PROWL 4E** to allow the addition of cotton post-directed layby applications in Arizona and Southern California to previously pendimethalin-treated cotton.

PM NOTE: If detectable residues of concern are found in cottonseed, a processing study for pendimethalin-treated cotton will be required.

cc: K. Dockter (CBRS), Pendimethalin Amended use & Reg. Std. files, C. Furlow (PBI/FOD), Circulation (7), RF.
RDI:ARRathman:9/16/91:EZager:9/16/91
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