



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

AUG 1 1994

8-1947,
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Reg.# 241-243. Response of 7/27/93 to Memo of G.J. Herndon Dated 1/6/93 Addressing the Request to Add Layby Use on Cotton to the Prowl®4E (Pendimethalin) Label.
(MRID# 428589-01, DP Barcode# D193629, CBTS# 12295)

From: G. Jeffrey Herndon, Chemist
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G. Jeffrey Herndon

Through: Richard A. Loranger, Acting Chief
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To: Edward Allen/Robert Taylor, PM Team 25
Fungicide/Herbicide Branch
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In response to an Agency letter dated 3/15/93, American Cyanamid Company has provided additional data surrounding the questions raised about the adequacy of the available storage stability data in support of the registrant's request for a label amendment. This action was previously evaluated by CBRS in memos from K. Dockter dated 7/3/89 and 9/18/91 and by CBTS in the memo of G.J. Herndon dated 1/6/93.

The registrant is requesting an amended registration for postemergence use of the herbicide pendimethalin on cotton. The current label allows up to 1.5 lbs.ai/A. to be used preplant only; the label clearly states "DO NOT APPLY PROWL® AS A POSTEMERGENCE SPRAY IN COTTON". The proposed label would allow, in Arizona and Southern California only, the additional use of 0.5 lb.ai./A. in 10 to 40 gpa. in previously pendimethalin-treated cotton. Protective shields are to be used to prevent spray contact with cotton foliage and stems.

A tolerance has been established for the combined residues of pendimethalin [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine] and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol in or on cottonseed at 0.1 ppm (40 CFR 180.361).



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Data were previously reviewed from a magnitude of the residue study reflecting application of Prowl® 4EC at the rate of 1.5 (and also 3.0) 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. At a method sensitivity of 0.05 ppm, residues were reported as non-detectable in all samples (see memo of K. Dockter dated 9/18/91, MRID# 418812-01).

In the memo of G.J. Herndon dated 1/6/93, CBTS concluded that the available storage stability data on soybean seed (a similar oily matrix to cottonseed, for which no storage stability data is available) indicate that levels of pendimethalin (CL 92,553) fell to roughly half of the starting concentration after only 12 months of storage. CBTS requested that the registrant submit various chromatograms from MRID# 418812-01 in order that the adequacy of the present tolerance level of 0.1 ppm of pendimethalin on cottonseed may be assessed in light of the proposed additional layby use and observed losses of the chemical over time in soybeans (i.e. determine the approximate sample residue levels that fall between the method quantitation and detection limits). The registrant was also requested to explain how the 0.003 ppm detection limit was determined and to specify if the data from the three studies in MRID# 418812-01 were generated using the shields that are specified in the proposed label.

Current Submission

In the current submission, the registrant has provided chromatograms and explanations to the requests cited above.

It appears that the lab analyzing the samples programmed in a minimum height of about 1200 counts resulting in a chromatograph report sheet that does not integrate any peak with a height count of at least 1200. This conclusion is based on the fact that the smallest peak that was integrated in any of the chromatograms provided was 1285 counts in height. Based on the peak height count of the standards and spikes, CBTS estimates a detection limit of about 0.01 ppm based on how the integrator was programmed; if the integrator's height reject had been set lower, CBTS might have been able to estimate a lower limit of detection (not quantitation). The petitioner estimates that the method detection limit is 0.003 ppm. Based on the data submitted, the quantitation limit cannot be set below 0.05 ppm, which is the lowest level that a matrix spike was analyzed and adequate recovery achieved.

In reviewing the chromatograms requested, CBTS notes that none of the field samples exhibited peak height counts above 1285 in the retention time window of either pendimethalin or its regulated metabolite. CBTS believes that the data support that no pendimethalin or its regulated metabolite was detected in the

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samples at or above 0.01 ppm. Therefore, even assuming that levels of pendimethalin in samples stored for 12 months are only half of their starting concentration, CBTS believes that the data support a 0.1 tolerance, even though the limit of quantitation is only 0.05 ppm.

In response to the question concerning whether the residue data were generated using the shields that are specified in the proposed label, the petitioner responded the treatments were directed to the soil between the rows, but shields were not used. The petitioner concludes that, because direct contact of the cotton plants with the spray is reduced when shields are used, the residue trials are representative of a worse-case situation.

Conclusions and Recommendations

Based on the additional data supplied with this submission, CBTS does not expect residues of pendimethalin to exceed the 0.1 ppm tolerance on cottonseed. CBTS has no objections to this proposed amended registration of Prowl 2E® to allow the addition of cotton post-directed layby applications in Arizona and Southern California to previously pendimethalin-treated cotton.

cc: RF, Pendimethalin Amended Use and Reg.Std. files, circu.,
PP# 5F1556, G.J. Herndon, E. Haeberer (section head).

RDI: Section Head: E. Haeberer: 7/29/94,
Acting Branch Senior Scientist: 7/29/94,
Acting Branch Chief: R. A. Loranger: 8/1/94.

H7509C: CBTS: G. Herndon: 305-6362: CM#2: Rm 804C: 7/29/94.