

US EPA ARCHIVE DOCUMENT

108501

Date Out EFB: 10 JAN 1984

TO: Robert Taylor
Product Manager
Registration Division
TS-767

FROM: Sam Creeger, Chief *SK*
Review Section No. 1
Exposure Assessment Branch
Hazard Evaluation Division

Attached please find the environmental fate review of:

Reg./File No.: 241-EUP-RNU

Chemical: Pendimethalin

Type Product: Herbicide

Product Name: Prowl

Company Name: American Cyanamid

Submission Purpose: Response to previous EAB review for
use on onions and garlic

ZBB Code: ?

ACTION CODE: 751

Date in: 12/19/83

EFB # 4 128

Date Completed: 1/10/84

TAIS (level II) Days

62

1

Deferrals To:

 Ecological Effects Branch

 Residue Chemistry Branch

 Toxicology Branch

1.0 INTRODUCTION

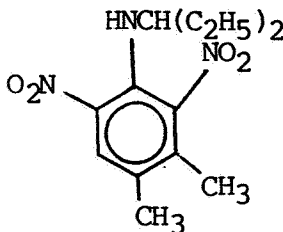
The registrant, American Cyanamid has submitted a response to the 5/25/83 EAB review of their application for an experimental use permit for testing Prowl Herbicide (Pendimethalin, as a. i.) on dry bulb onions (direct seeded only) and garlic. The response deals with the rotational crop restriction revision requested by EAB.

1.1 Chemical

Common name: Pendimethalin

Chemical name: N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine

Chemical structure:



2.0 DIRECTIONS FOR USE

Use directions and description of the experimental program are included in the 5/25/83 EAB review of the experimental use permit application.

3.0 DISCUSSION

The registrant's original submission and EAB recommendation, the registrant's reply and EAB response follow, in that order:

3.1 Registrant's original submission

The proposed rotational crop restriction follows that on the current approved label- namely, winter wheat and winter barley may be planted in the fall 120 days after a PROWL application in onions or garlic.

(Note: Other crop restrictions apply, but this review concerns only the above. See complete label appended to the 5/25/83 EAB review.)

3.2 EAB recommendation:

EAB does not object to the issuance of the experimental use permit provided the proposed rotational crop restriction is revised to read: Winter wheat and barley may be planted one year after Prowl application. Bulb onions, garlic and crops for which Prowl is currently registered may be planted earlier than one year after Prowl application.

Rotational crop data submitted were studies in which the rotational crops were planted in soil treated with Prowl one year after treatment, not 120 days after treatment.

3.3 Registrant's reply

The rotational crop restriction does not need to be revised. The EPA registered the follow crop statement on October 16, 1980. The labeling was also accepted in the PROWL D51 label revision on September 27, 1982.

3.4 EAB response

3.4.1 Background

The registrant previously requested a change in registration to permit follow crop planting of winter wheat and winter barley after a Prowl spring application in field corn, cotton, soybeans and transplanted tobacco (where registered under 24(c)). Data were submitted to support the request.

The submitted data were reviewed by EFB on 6/19/80. EAB concurred with the request even though two objections to the data were raised: "No accumulation data for grain alone were presented. Accumulation in grain may have been masked by the analysis of whole plants," and (2) "A study using radiolabeled Prowl was not done and the only degradate assayed for was CL 202, 347, which is only one of several notable soil degradates of Prowl. It is therefore possible that other Prowl degradates accumulated in the study but went undetected under the analytical protocol."

In spite of these objections, the EFB concurrence was based on the fact that "since past submissions on rotational crops have been approved based on the same analytical approach, these objections are not sufficient to cause rejection of the requested change in rotational crops permitted with Prowl." EFB concluded that residues in winter wheat and barley would not be above the level of analytical method sensitivity.

EAB noted in the 5/25/83 review that rotational crop data submitted (and accepted) were studies in which the rotational crops were planted in soil treated with Prowl one year or more after treatment, not 120 days after treatment. These studies were reviewed by EAB 4/24/74.

3.4.2 Conclusion

The rotational crop data supporting the 120 day rotational crop restriction for winter wheat and barley are of minimal value. The objections raised by the review 6/19/80 are valid and thus, compromise the conclusions. It should be noted that the studies were accepted only because other data with similiar deficiencies in past submissions had been accepted. In the opinion of this reviewer, the studies should be re-done.

However, for the current action, EAB will accept the submitted rotational crop data for winter wheat and barley as supporting the proposed rotational crop restriction as given on the label for the proposed experimental use permit.

This acceptance is based on the fact that the registration of Prowl already allows winter wheat and barely to be planted 120 days following the major crops: field corn, cotton, and soybeans. In the past EFB review, this revision was accepted even though EFB had objections to the data supporting this change. It had been past EFB policy to accept such studies since past studies had been accepted having deficiencies/objections similar to those raised.

Also, the proposed experimental use permit is for a relatively limited acreage (1,210 acres) for testing Prowl on dry bulb onions and garlic (crops which could be considered minor crops).

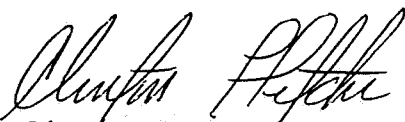
4.0 RECOMMENDATION

EAB continues to have no objection to issuance of the proposed experimental use permit for testing Prowl on dry bulb onions and garlic.

The rotational crop restriction allowing the planting of winter wheat and barley 120 days after treatment is adequate for the proposed experimental program. However, EAB finds the following deficiencies in the studies:

1. No accumulation data in grain alone were presented. Accumulation in grain may have been masked by the analysis of whole plants.
2. A study using radiolabeled Prowl was not done and the only degradate analyzed for was Cl 202, 347, which is only one of several notable soil degradates of Prowl. The presence of other degradates may have gone undetected by the analytical procedure.

The registrant should be informed of the deficiencies in the studies for winter wheat and barley and that additional uses proposed for Prowl in the future may engender a complete reassessment of these studies.



Clinton Fletcher
Review Section No. 1
Exposure Assessment Branch
Hazard Evaluation Division