

DATE:

SUBJECT: Addition of Prowl applied preplant incorporated in transplanted tobacco

FROM: Robert J. Taylor, Product Manager 25  
Fungicide-Herbicide Branch, Registration Division (TS-767)

TO: Douglas D. Camp, Director  
Registration Ddivision (TS-767)

THRU: James W. Akerman, Branch Chief *JWA*  
Fungicide-Herbicide Branch, Registration Division (TS-767)

Issue

Should the Agency add tobacco to the registered uses for Prowl Herbicide containing a nitrosamine.

Background

On April 5, 1979, the Agency received an application for amended registration requesting the addition of transplant tobacco to the label for pendimethalin [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzeneamine]-Prowl herbicide.

The data submitted in support of this amendment included:

1. a 21-day subacute inhalation study
2. residue data from Georgia, Kentucky, Virginia, Pennsylvania, and North Carolina in tobacco (green and cured) and smoke condensate.

Additional data on file include:

1. acute oral LD50, rats
2. acute dermal LD50, rabbits
3. skin and eye irritation, rabbits
4. 21-day dermal, rabbits
5. 90-day feeding study, rats
6. 90-day feeding study, dogs
7. 18-month oncogenesis, mice
8. 2-year chronic feeding/oncogenesis
9. 3-generation reproduction, rats
10. dominant lethal study
11. effect on male mammary glands

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12. teratology, rats
13. cataractogenic study
14. Ames mutogenicity assay
15. host mediated assay, mice
16. manufacturing and formulation data
17. nitrosamine data
18. dinitrosation procedures
19. residue data on corn, cotton, soybeans, potatoes, and grain sorghum

#### Discussion

Prowl is a herbicide registered for use in cotton, soybeans, and corn. On April 5, 1979, the Agency received a request to add a use for tobacco. This amendment was reviewed by Residue Chemistry and Toxicology Branch. The conclusions of the Residue Chemistry Branch were that residues of pendimethalin in cured tobacco by the proposed use would be less than the sensitivity of the analytical method, 0.1 part per million. Residues in cigarette smoke would be considerably lower than 0.1 part per million. The Toxicology Branch declared the 21-day subacute inhalation study invalid. Since Residue Chemistry reported that no residues were present in smoke this comment is not pertinent.

The product contains a nitrosamine [REDACTED]

[REDACTED] Based on a risk assessment performed by the Agency, it has been concluded that if the nitroso contaminant in Prowl were not in excess of 135 ppm, the upper level of risk would not exceed  $1 \times 10^{-6}$ . This has been concluded to be an acceptable level of risk.

In a letter of March 17, 1980, the Agency notified the Company that if the level of nitrosamine in Prowl would be kept at or below the 135 ppm level, the tolerances would be established for grain sorghum and potatoes. On April 18, 1980, information was submitted to the Agency on denitrosation procedures to support the required level. A final decision awaits review of these procedures.

#### Alternatives

1. To add the use for transplanted tobacco to the label.
2. Do not accept the tobacco use at this time.

#### Conditions

The level of the nitrosamine contaminant in Prowl be kept at or below 135 ppms.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

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Recommendation

Since we are prepared to grant tolerances and conditional registrations for Prowl in potatoes and grain sorghum, we recommend the use for tobacco be accepted.

*Vickie K Walters*  
for Robert J. Taylor  
Product Manager 25  
Fungicide-Herbicide Branch  
Registration Division (TS-767)

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Concur

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Do not concur

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Date

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