

MEMORANDUM

SUBJECT: ID # 3125-422 - Imidacloprid on Tobacco. Amended Registration Request and the 3/26/96 Amendment. Submission of Residue Data. MRID# 439704-01. Barcode D227016. Chemical 129099. Case 104226.

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11/21/96

**THRU: E.T. Haeberer, Acting Branch Chief
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**TO: Donna Davis, Chemical Manager
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Bayer Corporation, Agricultural Division, in a letter dated May 31, 1995, proposed to amend the registrations of Admire® 2 F and Provado® 1.6 F to add non-food uses on tobacco. In the February 26, 1996 amendment, the petitioner revised both labels adding a 14-day PHI and provided a written summary of the magnitude of the imidacloprid residue data on green and cured tobacco leaves. The current amendment (3/26/96) consists of the final report of the residue data, as requested in CBTS's previous review (Memo, F. Griffith 2/29/96). The identities of residues in mainstream and sidestream smoke as determined in the pyrolysis study are discussed in the 2/29/96 Memo.

Executive Summary of Chemistry Deficiencies

• None •

RECOMMENDATIONS

Toxicological considerations permitting, CBTS recommends for the registration of imidacloprid for use on tobacco. However, HED notes that the Food Quality Protection Act of 1996 has amended and strengthened the standard for establishing registrations under the FFDCA. OPP is still assessing the full impact of this change in the law on the registration-granting process and plans to issue

guidelines concerning the establishment of registrations under the amended statute. All amended registrations for pesticides with food uses have to meet the requirements of the FIFRA as amended by the FQPA and OPP may require additional data to determine if the terms of the amended statute are met. Although CBTS is recommending in favor of this amended registration at this time, that recommendation will be subject to review as OPP develops guidelines under the amended statute.

CONCLUSIONS

1. The residue trials were conducted in North Carolina, South Carolina, and Georgia (3 trials in Region II); and 2 trials in Kentucky (Region V). At 14-days PHI total imidacloprid residues ranged from 0.9 ppm to 4.1 ppm, averaging $2.5 \text{ ppm} \pm 1.2 \text{ ppm}$ on green tobacco leaves. The maximum value observed at 21-days PHI was 6.2 ppm. On cured tobacco leaves total imidacloprid residue ranged from 15.2 to 30.7 ppm at 14-days PHI, averaging $21.9 \pm 5.9 \text{ ppm}$.

2. Based on the crop field trial data, CBTS concludes that total imidacloprid residues are not expected to exceed 6 ppm on green tobacco leaves and 31 ppm on cured tobacco leaves when Admire and/or Provado is used as directed. With this information we can recommend for a permanent registration of imidacloprid on tobacco.

DETAILED CONSIDERATIONS

Deficiency - Conclusion 3 (from Memo, F. Griffith 2/29/96)

3. The petitioner needs to submit the final complete results of the 5 tobacco crop field trials. Based on the summary of the crop field trial data CBTS tentatively concludes that total imidacloprid residues on tobacco leaves are not expected to exceed 7 ppm on green tobacco leaves and 31 ppm on cured tobacco leaves when Admire and/or Provado is used as directed.

Petitioner's Response: Submission of:

Imidacloprid (240FS) - Magnitude of the Residue on Tobacco. MRID# 439704-01.

The trials were conducted in North Carolina, South Carolina, and Georgia (3 trials in Region II); and 2 trials in Kentucky (Region V). In each field trial tobacco plants were treated with Admire 2F at a rate of 0.02 lb ai imidacloprid at transplanting followed by 3

foliar applications at a rate of 1.5 ozs ai imidacloprid per acre per application ($\approx 2X$). Green tobacco leaves were harvested at 0, 7, 14, and 21 days after the third application. Sample analysis for imidacloprid was performed using the GC/MS analytical enforcement method. The method was validated over a range of 0.05-60 ppm. The average recovery was $109 \pm 3\%$ in green leaves and $100 \pm 11\%$ in cured leaves. At 14-days PHI total imidacloprid residues ranged from 0.9 ppm to 4.1 ppm, averaging $2.5 \text{ ppm} \pm 1.2 \text{ ppm}$ on green tobacco leaves. The maximum value observed at 21-days PHI was 6.2 ppm. On cured tobacco leaves total imidacloprid residue ranged from 15.2 to 30.7 ppm at 14-days PHI, averaging $21.9 \pm 5.9 \text{ ppm}$.

CBTS's Conclusion: Based on the crop field trial data, CBTS concludes that total imidacloprid residues are not expected to exceed 6 ppm on green tobacco leaves and 31 ppm on cured tobacco leaves when Admire and/or Provado is used as directed. The requested information has been provided. This deficiency is now resolved. With this information we can recommend for a permanent registration of imidacloprid on tobacco.

cc: Kramer, Circ., R.F., D. Edwards/P. Jenkins (RD, 7505C)
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