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

11/21/89

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#7E3489 - CGA-154281 on All Crops with Tolerances for Metolachlor (Dual®).
Evaluation of the Second Petition Method Validation (PMV) Report.
(No MRID Nos.)[No DEB Nos.]{No Project Nos.}

From: Francis D. Griffith, Jr., Chemist
Dietary Exposure Branch
Health Effects Division (H7509C)

Thru: Robert S. Quick, Section Head
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (H7509C)

To: Kerry Leifer, PM-45
Registration Support Branch
Registration Division (H7505C)

The Dietary Exposure Branch (DEB) has been informed by the Analytical Chemistry Section, Analytical Chemistry Branch (ACB) of the completion of the requested second CGA-154281 petition method validation (PMV). The results of the PMV were reported by D. M. Swineford and C. J. Stafford in their memorandum dated October 27, 1989.

The second PMV was requested for CGA-154281 [4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxozine] in corn forage (see memorandum by F. D. Griffith, Jr. dated September 6, 1989 to ACB/BEAD). The PMV for CGA-154281 on corn forage was requested for the Ciba-Geigy method AG-536C dated August 18, 1989 and titled "Analytical Method for Determination of CGA-154281 in Crops by Capillary Chromatography."

The PMV was conducted using the petitioner's method as supplied by DEB. No minor modifications were noted on the report form, thus ACB ran the method as written. DEB on reviewing the copies of the ACB GC chromatograms agrees that the CGA-154281 limit of detection appears to be 0.005 ppm in corn forage. There were matrix coextractives or unidentified analytical responses (UARs) that could interfere with the CGA-154281 determination.

ACB commented that if certain GC parameters were slightly modified a better separation of CGA-154281 from corn UAR's is obtainable. ACB also commented that different capillary GC columns may allow for better separation of the UARs from CGA-154281. These comments will be forwarded to FDA for publication in PAM-II (see comments 2, 3, and 4).

ACB also noted the instructions for dissolving the sample in a 0.5 ml solvent volume for GC analysis. DEB agrees with ACB that when using auto sampler injection that the method user should be reminded to use the micro sample vial, otherwise in a 2 ml standard vial adequate sample will not be available. This comment will be forwarded to FDA for publication in PAM-II.

DEB requested the CGA-154281 method be validated at 0.01 ppm and 0.02 ppm in corn forage. CGA-154281 recoveries ranged from 79% to 114% with an average recovery of 95% from 6 determinations. DEB concludes from the above data there has been a successful PMV. The CGA-154281 in corn forage method is suitable to gather CGA-154281, per se, residue data and to enforce the CGA-154281 tolerances in all crops that have metolachlor tolerances.

The analytical reference standard is available from EPA's Pesticides and Industrial Chemicals Repository at RTP-NC. The code number is F-927. In this PMV the standard did not show extraneous peaks, thus it is suitable for RTP distribution.

ACB reports that a skilled residue analyst with all of the necessary equipment in place should be able to prepare a set of 6 samples within 8 hours and complete the analysis with ALS-GC overnight. This is consistent with the time frame the petitioner has reported. DEB considers this time frame is within our Guidelines and is satisfactory for regulatory work.

CONCLUSION

DEB concludes the method AG-536C proposed for enforcement of CGA-154281 tolerances in all crops that have metolachlor tolerances has had a successful PMV. The method is suitable to gather residue data and enforce tolerances.

The deficiency on the PMV noted in our review of Sept. 5, 1989 by F. D. Griffith, Jr. is resolved. There are no residue chemistry deficiencies remaining for PP#7E3489.

2

RECOMMENDATION

DEB recommends the analytical method for CGA-154281 residues be forwarded to FDA's Technical Editing Group for Publication in PAM-II, and be forwarded to ISB/PMSD to be made available to all interested parties.

DEB recommends for the proposed tolerance of CGA-154281 at 0.01 ppm on all crops that have metolachlor tolerances. If CGA-154281 is incorporated into metolachlor formulations and used as directed then residues of CGA-154281 are not expected to exceed the proposed 0.01 ppm tolerance.

H7509C:DEB:Reviewer(FDG):CM#2:Rm814B:557-0826:BB:11/16/89:
edited:fdg:11/16/89.

cc: R.F.; Circu (7); Reviewer (FDG); PP#7E3489: R. F. Thompson (RTP-N.C.); CGA-154281 Sub. File; TOX; FDA (Corneliussen-HFF-426); PM-45; M. Bradley (PMA-II coeditor/ MTO File); Dean Hill (OCM-NEIC-Denver); D. A. Marlow (ACB/BEAD); ISB/PMSD (Eldredge); E. B. Claussen (OSW-ANR-445).

RDI:Section Head:R. S. Quick:11/16/89:R. A. Loranger:11/16/89.