Reg. Std 7. 4-25-90

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

APR 25 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Leon Sawyer, Chemist
Pesticides and Industrial Chemicals Branch (HFF-426)
Division of Contaminants Chemistry
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Dear Leon:

Enclosed is the following Multiresidue Method (MRM) test information for updating a future addition of PAM-I, Appendix I:

Title: "Determination of the Metalaxyl Metabolites CGA-100255 and CGA-94689 (A and B Isomers) By U.S. Food and Drug Administration Multiresidue Procedures"
H. Lee Hubbard Author
February 24, 1989
78 pages
Laboratory Project ID ABR-88156

Chemical: Metalaxyl*

Type: Fungicide

Protocols: I, II, III, and IV

Company: Ciba - Geigy Corporation
Agricultural Division
Post Office Box 18300
Greensboro, N.C. 27419

Performing Laboratory: same

PP No: 8F 3617/8H 5554

MRID: 410552-03

40CFR References: 180.408, 185.4000, and 186.4000

*N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester

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These MRM data are for 2 metalaxyl metabolites. Previously DEB Had forwarded MRM data for parent metalaxyl and metabolites CGA-6286 and CGA-37734 through MRM Protocols I through IV (see letter from Dr. M.J. Nelson to L. Sawyer dated May 17, 1988, PP#5F3470/FAP#7H5520, Metalaxyl on Blueberries, Walnuts, Almonds, Almond, Hulls, Stone Fruits, Dried Apricots, and Prunes). In our review of that petition DEB requested these additional MRM recovery data for other metalaxyl metabolites.

I have scanned these data. These data were presented for Protocols I thru IV, not A through E. Much of the data can be translated from the Roman numeral protocols to the alphabet designation protocols. The petitioner has presented GC determination data using the various columns designated in protocols I, II, and III for EC and N/P, but not FPD-S detector as there is no S in the molecules. The metabolites could not be recovered through Florisil using either elution system. Adequate detection could not be obtained for these metabolites using post column OPA derivatization fluorescence detection. The metabolites can be recovered using the Luke method (and Storherr method) but not necessarily at very low sensitivity levels.

If upon examination these data you consider what has been submitted by Ciba Geigy Corporation to be deficient, please let me know what additional data FDA would require.

Sincerely,

Dick

Francis D. Griffith, Jr. Chemist
Dietary Exposure Branch
Health Effect Division (H-7509C)

Enclosure: Ciba Geigy Corporation, Project Identification ABR-88156.
"Determination of the Metalaxyl Metabolites CGA-100255 and CGA-94689 (A, and B Isomers) By U.S. Food and Drug Administration Multiresidue Procedures."
MRID# 410552-03

cc:(Without Enclosure): R.F., Circu (7), Reviewer (FDG), PP#8F3617/8H5554, PM-21 (Lewis), PAM-II Coeditor (M. Bradley), Metalaxyl Reg. Std. File, PP#5F3470/7H5520, PIB/FOB (Furlow)

H7509C:DEB:Reviewer (FDG):vg:CM#2:Rm814B:5570826:ed:fdg:4/16/90.
RDI:Section Head:R.S.Quick:4/16/90:R.D.Schmitt:4/18/90.

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