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

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MAY 10 1991

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Metalaxyl N-(2,6,-dimethylphenyl)-N-(methoxyacetyl)-alanine, methyl ester: Company Response.

Project No.: 1-0934
EPA Nos.: 113501
MRID No.: None

Tox. Chem. No.: 375AA
Submission No.: S393289
DP BAR CODE: D162813

TO: L.Rossi/C.Peterson, PM Team # 74
Registration Division (H7505C)

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THRU: Roger L. Gardner, Section Head
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REGISTRANT: CIBA-GEIGY, Agricultural Division, Greensboro, NC

II. Action Requested:

Review CIBA-GEIGY 90-Day Response in relation to a DCI for an acute inhalation study in rats (81-3) with technical Metalaxyl and comment on the applicability of this study to this chemical.

I. Conclusions:

Based on a review of the evidences provided by the registrant in their 90-Day response, TB concurs that an acute inhalation study is not feasible with Metalaxyl because this chemical cannot be prepared and tested in a respirable form. Therefore, the data requirement should be waived.

III. Background:

In an OPP Reregistration Standard publication for Metalaxyl (OPP No. 540/RS-88-117), the Agency has identified an acute inhalation study (81-3) with Metalaxyl technical as a data gap for the reregistration of pesticide products containing Metalaxyl [N-(2,6,-dimethylphenyl)-N-(methoxyacetyl)alanine, methyl ester] as the active ingredient. The registrant, CIBA-GEIGY, was asked to submit a study on the acute inhalation toxicity of technical grade

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Metalaxyl if this material is in a respirable form.

In its 90-Day response, dated December 23, 1988, the registrant presented the following evidences that technical grade Metalaxyl (95.2% ai) cannot be prepared and tested in a respirable form:

(i) Because of its low melting point (about 70° C), the registrant attempts to pulverize technical grade Metalaxyl to respirable size particles through both hammermilling and air milling met with great difficulties because the material kept melting and recrystallizing into lumps. A standard sizing of the resulting particles preparation with a Cilas granulometer was also not feasible because the solubility of metalaxyl in water (7000 ppm) was above the limit for the instrument. CIBA-GEIGY therefore microscopically examined the preparation and estimated that 75% of the particles were < 10 um. This preparation was sent to Stillmeadows Biological Testing Laboratories for an acute inhalation toxicity study in rats.

(ii) Stillmeadows Biological Testing Laboratories could not generate an aerosol from the test material. They stated that, in spite of vigorous mechanical shaking of the flasks containing the test product and the use of a vigorous stream of dry air, no test material could be detected in the rats' breathing atmosphere. Consequently the planned acute inhalation study with Metalaxyl technical was aborted.

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