



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

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JAN 28 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

Subject: An expedite Product Chemistry Review on
Metalaxyl Technical
EPA Reg. No.: 100-601

From: Radamés Lozada, Chemist
Product Chemistry Review Section
Registration Support Branch
Registration Division (H7505C)

To: Susan Lewis, PM 21
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Donald Stubbs, Acting Section Head
Product Chemistry Review Section
Registration Support Branch
Registration Division (H7505C)

Requestor: Ciba-Geigy

EPA Reg. No.: 100-601

EPA MRID No.: none

Pesticide Chemical Code: 113501

Company Code No.: none

Chemical Name: N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine
methyl ester

Common/Trade Name: Metalaxyl

Use: fungicide

Radamés Lozada

Donald Stubbs

Introduction:

This submission (from Ciba-Geigy dated January 9, 1991) is for Metalaxyl Technical which contains the active ingredient N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester. The registrant is proposing a change on the active ingredient nominal concentration from 90% to 96.9% in answer to a review done by Radamés Lozada of the Registration Support Branch, Registration Division (dated October 2, 1990). In that instance the registrant proposed a change on the active ingredient nominal concentration from 90% to 94%, but according to the submitted data the reviewer concluded the following:

"A final conclusion concerning the requested label change for Metalaxyl Technical from 90% of active ingredient (AI) to 94% can not be reached because of a discrepancy between the submitted data and the submitted CSF. According to the submitted data (The Preliminary Analyses) all the batches exceed the upper limit suggested for the active ingredient.

Furthermore, according to the submitted Preliminary Analyses it appeared that Metalaxyl Technical would support a label claim of 97%.

The registrant must submit an explanation of these discrepancies before a final conclusion can be reached."

This review will address the submitted data as it relates to the product chemistry data requirements.

Registrant's Discussion:

In answer to the previously mentioned review the registrant states in this submission that they understand the Agency's need for questioning these differences and that a nominal concentration of 96.9% for Metalaxyl Technical can serve as their label guarantee. The registrant submitted a new CSF (dated 1/8/91) and five new copies of the label that reflect the proposed change.

Conclusions:

The proposed change on the active ingredient nominal concentration from 90% to 96.9%, the submitted CSF (dated 1/8/91), and the label are acceptable and supported by the submitted data (MRIDs 41055201-01, -02).

Note to the PM:

The new CSF submitted by the registrant contains new impurities that were not disclosed in the currently accepted CSF. Before this amendment can be accepted, the data should be forwarded to the Toxicology Branch (HED) for review.