Shaughnessy No.: 108801
Date Out of EFGWB: SEP 15 1989

TO: F.D. Rubis
Product Manager
Registration Division (H7508C)

FROM:

Paul Mastradone, Section Chief
Environmental Chemistry Review Section #1
Environmental Fate and Groundwater Branch

THRU:

Henry Jacoby, Acting Chief
Environmental Fate and Groundwater Branch
Environmental Fate and Effects Division (H7507C)

Attached please find the EFGWB review of:

Reg./File # : 100-587

Chemical Name: Metolachlor

Product Type : Herbicide

Product Name : Dual

Company Name : CIBA-GEIGY

Purpose : Request for extension until 1 December 1989 for submission of field dissipation studies

Date Received: 6 April 1989 Action Code: 400

Date Completed: 15 September 1989 EFGWB No.90490

Total Reviewing Time (decimal days): 1.0

Deferrals to:
_____Ecological Effects Branch, EFED
_____Science Integration & Policy Staff, EFED
_____Non-Dietary Exposure Branch, HED
_____Dietary Exposure Branch
_____Toxicology Branch, HED

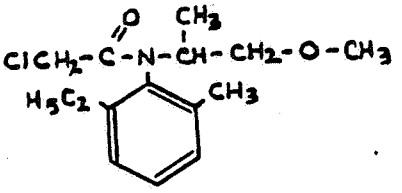
1.0 CHEMICAL:

Common Name: Metolachlor

Chemical Name: [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide]

Trade Name: Dual

Chemical Structure:



2.0 TEST MATERIAL: Not applicable. No studies submitted.

3.0 STUDY/ACTION TYPE:

Request by CIBA-GEIGY for extension until 1 December 1989 for submission of field dissipation studies.

4.0 STUDY IDENTIFICATION:

CIBA-GEIGY letter dated 1 March 1989 requesting an extension of field dissipation studies from 1 May 1989 to 1 December 1989. Received by HED on 5 April 1989.

5.0 REVIEWED BY:

George Tompkins
Entomologist, Review Section 1
EFGWB/EFED

Signature: George Tompkins
Date: 15 Sept 1989

6.0 APPROVED BY:

Paul Mastradone
Section Chief, Review Section 1
EFGWB/EFED

Signature: Paul J Mastradone
Date: SEP 15 19[illegible]

7.0 CONCLUSIONS:

EFGWB concludes that additional time is necessary to complete the Field Dissipation Studies. Since a new metabolite (CGA-50720) was identified late in the project, more time is necessary synthesize this new metabolite for inclusion in the analytical studies and the older soil metabolism samples have to be reanalyzed for the new metabolite.

8.0 RECOMMENDATIONS:

It is recommended that an extension be granted until 1 December 1989 for the submission of the Metolachlor Registration Standard requirement for Field Dissipation studies from CIBA-GEIGY.

9.0 BACKGROUND:

The metolachlor FRSTR, field dissipation studies with the typical end use product (EPA Guideline 164-1) are due to EPA on 1 May 1989. However, since a new metabolite was identified late in the studies, an extension is requested until 1 December 1989 to allow for synthesis of this metabolite and development of analytical methods for its detection as well as to reanalyze earlier samples for this new metabolite. This new work will cause the studies to be delayed beyond the 1 May 1989 due date.

10.0 DISCUSSION OF INDIVIDUAL STUDIES:

Not applicable. No studies were submitted.

11.0 COMPLETION OF ONE-LINER:

Not applicable

12.0 CBI APPENDIX:

Not applicable

Agricultural Division
CIBA-GEIGY Corporation
P.O. Box 18300
Greensboro, North Carolina 27419
Telephone 919 292 7100

CIBA-GEIGY

March 1, 1989

Mr. Lawrence J. Schnaubelt
Acting Product Manager (23)
Registration Division (TS-767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M. Street, S.W.
Washington, D.C. 20460

Dear Mr. Schnaubelt:

SUBJECT: METOLACHLOR REGISTRATION STANDARD
REQUIREMENT FOR FIELD DISSIPATION
STUDIES
REQUEST FOR EXTENSION

Under the Metolachlor FRSTR, field dissipation studies with the typical end use product (EPA Guideline 164-1) are due to the Agency on May 1, 1989. The purpose of this letter is to request an extension of that deadline to December 1, 1989 due to circumstances beyond CIBA-GEIGY's control.

Attached is a letter from the laboratory conducting these studies, Agrisearch, Inc., which outlines the reasons for the extension request. Primarily, additional time is needed because new metabolites were identified during the course of the soil metabolism study. Because the field dissipation studies were running concurrently with the soil metabolism work, the analysis of the field dissipation samples was delayed until the new metabolites could be synthesized and analytical methods developed.

In addition, another new metabolite was identified late in the studies (April, 1988) for which a method had to be developed. Samples analyzed earlier are having to be reanalyzed for the new metabolite. All this additional work will cause the studies to be delayed beyond the May 1, 1989 due date.

To ensure that CIBA-GEIGY would submit acceptable field dissipation studies, noting the difficulties with the ones discussed above, four additional studies were initiated at two other sites with another laboratory conducting the analyses. These studies are planned for completion in November, 1989.

Therefore, CIBA-GEIGY respectfuly requests an extension to

December 1, 1989 for submission of the original plus the new studies. Because California has granted us a similar extension based upon the above information, CIBA-GEIGY trusts the Agency will be able to do the same.

Thank you for your handling of this matter.

Sincerely,

Karen S. Stumpf

Karen S. Stumpf
Senior Regulatory Specialist
Regulatory Affairs

Attachment

cc: Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
U.S. Environmental Protection Agency
401 M. Street, S.W.
Washington, D.C. 20460

AGRISEARCH INCORPORATED

RESEARCH FARM
Mt. Airy, MD 21771

LABORATORIES
26 Water Street
Frederick, MD 21701
301-662-2203

February 24, 1989

R.A. McLaughlin, Ph.D.
Environmentalist II
Residue Chemistry Department
CIBA-GEIGY Corporation
P.O. Box 18300
Greensboro, NC 27419

Dear Dr. McLaughlin:

We request that you obtain an extension from the United States Environmental Protection Agency (EPA) for the submission of the Dual 8E Field Dissipation Studies (Agrisearch Projects 1264 and 1265). The following reasons are cited for the needed time extension:

(1) There were new metabolites found in the ^{14}C-Metolachlor Soil Metabolism Study (CGA-40172, CGA-51202, and CGA-40919). This required identification studies and synthesis of these potential metabolites. Once standards were obtained, an analytical method had to be developed for each of these metabolites. This delayed analysis of field samples, since the laboratory metabolism and field dissipation studies were running concurrently.

(2) We had a sufficient quantity of CGA-40172 and CGA-40919 standards for storage stability and method development work. However, there was a substantial delay in obtaining additional quantities of standards for daily laboratory recovery spiking. This slowed routine analysis of soil samples.

(3) A new metabolite (CGA-50720) was identified late in the project (April, 1988) and this chemical required additional synthesis (July, 1988) and method development efforts (July/August, 1988).

(4) We are currently analyzing samples on the project and are beginning to organize for the reanalysis of samples from early time points, to obtain residue information for the new metabolite (CGA-50720).

It is important that EPA understand that a Dual 8E submission extension will allow for the orderly completion of this project.

Please keep me advised of your communication with the EPA.

Sincerely,

D. Larry Merricks, Ph.D.
President

DLM/bb