

US EPA ARCHIVE DOCUMENT

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 PC Code No. :090501
 EFGWB Out : 2/19/93

TO: Ann Sibold
 Special Review and Reregistration Division (H7508W)

FROM: Elizabeth Behl, Head
 Ground Water Technology Section
 Environmental Fate & Ground Water Branch/EFED (H7507C)

THRU: Henry Jacoby, Chief
 Environmental Fate & Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of...

Reg./File # : _____

Common Name : Alachlor

Product Name : Lasso

Company Name : Monsanto Agricultural Group

Purpose : Special Review Data (870); Product Specific Data (Reregistration-655); Generic Data (Reregistration-660)

Type Product : Herbicide

Action Code : 870/660 EFGWB #(s): 90-437; 90-0657 Total Review Time = 8 days

EFGWB Guideline/MRID/Status Summary Table: The review in this package contains...

161-1	162-4	164-4	166-1
161-2	163-1	164-5	166-2
161-3	163-2	165-1	166-3
161-4	163-3	165-2	167-1
162-1	164-1	165-3	167-2
162-2	164-2	165-4	201-1
162-3	164-3	165-5	202-1

Y = Acceptable (Study satisfied the Guideline)/Concur P = Partial (Study partially satisfied the Guideline, but additional information is still needed)
 S = Supplemental (Study provided useful information, but Guideline was not satisfied) N = Unacceptable (Study was rejected)/Non-Concur

1. CHEMICAL

Common name: Alachlor
 Chemical name: 2-Chloro-2'-6'-diethyl-N-(methoxymethyl)-acetanilide

2. TEST MATERIAL:

Not applicable.

3. STUDY/ACTION TYPE:

Review of large scale retrospective ground water monitoring study,
 National Alachlor Well Water Survey (NAWWS).

4. STUDY IDENTIFICATION:

Author & Title(s): Holden, L.R. and J.A. Graham, 1990. "The National
 Alachlor Well Water Survey." Volumes 1-7.

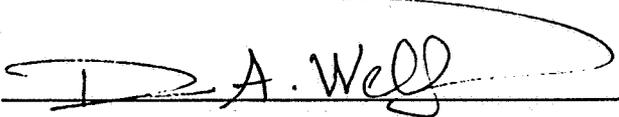
EFGWB: 90-437
 Pack Number: 50229
 Identifying Number: 090501-8
 Record Number: 260721
 Action Code: 660

EFGWB: 90-0657
 Pack Number: 50693
 Identifying Number: 090501-8
 Record Number: 266119
 Action Code: 870

Documents submitted by:

Monsanto Agricultural Company
 St. Louis, Missouri 63167

5. PREPARED BY:

David Wells Signature: 
 Hydrologist
 EFED/Ground-Water Technology Section - Date: 2/18/93

6. APPROVED BY:

Elizabeth Behl Signature: 
 Section Head
 EFED/Ground-Water Technology Section - Date: 2/19/93

7. CONCLUSIONS:

The results of the NAWWS study found few detections of alachlor in ground water. It is estimated that less than one percent of the six million wells contained detectable levels of alachlor, and an estimated 0.02 percent exceeded the MCL of 2 ug/L. Monsanto estimates that this represents slightly more than 3,000 people who are exposed to alachlor levels above the MCL of 2 ppb (ug/L).

The 1990 Monsanto NAWWS study suggests that the parent compound alachlor is not commonly found in private rural drinking water wells in its use area. However, no major studies have focused on alachlor degradates/metabolites under field conditions.

8. RECOMMENDATIONS:

Please see attached document entitled "Review of the Monsanto Company National Alachlor Well Water Survey-Phase II Report." EPA Contract No. 68-D8-0006. Fairfax, VA: ICF Incorporated.

9. BACKGROUND:

Alachlor is a pre-emergent soil applied herbicide used principally in the spring on corn, soybeans and peanuts. It has approximately the second highest volume of use of any pesticide in the United States.

EPA expressed concern about potential alachlor contamination of surface and ground water and requested the registrant, Monsanto, to conduct monitoring studies.

In 1985, Monsanto designed a statistically-based, large-scale retrospective ground-water sampling program similar to EPA's National Pesticide Survey. This study, termed the "National Alachlor Well Water Survey" (NAWWS), sampled private, rural drinking water wells in alachlor use areas for detectable levels of alachlor at or above 0.2 ppb. Monsanto collected extensive data from the sampling areas and ground-water samples from 1,430 wells. This statistical sampling of wells represented over 6 million private, rural, domestic wells in the alachlor use area, serving 6.5 million households and twenty million people.

10. DISCUSSION:

The Monsanto NAWWS study sampled 1,430 drinking water wells for five pesticides and nitrate. EPA had requested that Monsanto conduct a statistically based sampling of drinking water wells for alachlor. Monsanto elected to analyzed for four additional pesticides and nitrate in the study. The four additional pesticides were atrazine, cyanazine, metolachlor and simazine. No metabolites of alachlor were analyzed.

A review of the Monsanto NAWWS study conducted by ICF focused on QA/QC by auditing selected raw data, reviewing the validity of the conclusions on population risk estimates, determining if the conclusions from the alachlor use area can be extrapolated to the similar atrazine use area and, a statistical analyses of meteorological data, and identifying and evaluating factors that may affect alachlor contamination in ground water.

The raw data for Wayne County, North Carolina was selected for audit. The analytical packages from Monsanto were found to be complete with all the necessary supporting quality assurance/quality control data. The data was found to be poorly organized, however it generally meet all criteria for accuracy, precision, sensitivity and completeness for QA/QC.

The NAWWS was designed to estimate the number of wells containing herbicides and nitrate, not the number of people exposed to these chemicals. Since the study does not directly measure exposure directly, a number of assumptions were made to correlate contaminated wells and exposed people which is detailed in the attached report. Exposure estimates were verified for Wayne County, North Carolina.

ICF's review found one serious "anomaly" in the data. One well was reported to serve 52 people when the value should have been 4. Because of the low weighting of the observation it is believed that this did not significantly impact any exposure estimates or other conclusions. No other significant errors were found in Monsanto's exposure estimates.

The results and conclusions are only valid for the population of wells defined in the alachlor use area. ICF examined the sampling design, and other potential sources of bias. The sampling design conformed to accepted statistical practices and potential sources of bias were minimized. The sampling design was appropriate for the original goals of the study. Using the available data, ICF could not determine if the alachlor results would apply to the atrazine use areas. It was also determined that the NAWWS results can not used in estimating national exposures.

Generally the use of water table height (depth to water) was not effective in assessing the relationships between ground-water recharge conditions and the occurrence of pesticides in the wells. ICF developed an alternative subsurface recharge data set using weather data from the National Climatic Data Center. Generally the occurrence of any of the five pesticides, and nitrate were found to associated with some part of subsurface recharge condition. ICF also identified a number of additional factors that could affect alachlor contamination of ground water.



United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460
Data Review Record
Confidential Business Information - Does not contain
National Security Information (E.O. 12065)

Pack Number

50693

Date Received

6/25/90

1. Product Name

Alachlor

Chemical Name 2-chloro-2-(6-dimethylamino-1-hexylurea)-1,1-dichloroethane

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
090501-8	266119	870		Description of the first and second stage aquatic toxicity for 3 countries in the NAWWS.

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
1	6/15/90	<i>Duffy Finn</i> <i>Duffy S. Wald</i>	72	6/19/90	7/6/90	

Instructions

Please review for adequacy to fulfill the additional data request. Also review for quality of data and value of test procedures.

Please pass package to other team members who may be interested in reviewing this material.

This Section Applies to Review of Studies Only

14. Check Applicable Box	15. No. of Individual Studies Submitted
<input type="checkbox"/> Adverse 6(a)(2) Data (405) <input checked="" type="checkbox"/> Special Review Data (870)	3 attachments 1 - printout
<input type="checkbox"/> Generic Data (Reregistration)(660) <input checked="" type="checkbox"/> Product Specific Data (Reregistration)(655)	

16. Have any of the above studies (in whole or in part) been previously submitted for review?	17. Related Actions
<input checked="" type="checkbox"/> Yes (Please identify the study(ies)) 3 illustration of sample selection issue for NAWWS	
<input type="checkbox"/> No	

18. To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED	Science Analysis & Coordination	SAC <input type="checkbox"/> PC <input type="checkbox"/>	A. Policy Note No. 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements
	Toxicology/HFA	TOX/HFA <input type="checkbox"/> PL <input type="checkbox"/>	
	Toxicology/IR	TOX/IR <input type="checkbox"/>	
	Dietary Exposure	DEB <input type="checkbox"/> EA <input type="checkbox"/>	
	Nondietary Exposure	NDE <input type="checkbox"/> AC <input type="checkbox"/> BA <input type="checkbox"/>	
EFED	Ecological Effects	EEB <input type="checkbox"/>	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18
	Environmental Fate & Groundwater <i>D. Wells</i>	EFGWB <input type="checkbox"/>	
SRRD	Special Review	SR <input type="checkbox"/>	
	Reregistration	RER <input type="checkbox"/>	
	Generic Chemical Support	GSC <input type="checkbox"/>	
RD	Insecticide-Rodenticide	IR <input type="checkbox"/>	C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
	Fungicide-Herbicide	FH <input type="checkbox"/>	
	Antimicrobial	AM <input type="checkbox"/>	
	Product Chemistry		
BEAD	Precautionary Labeling		
	Economic Analysis		
	Analytical Chemistry		
	Biological Analysis		

Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets) Label Attached

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