

Shaughnessy No.: 108801

Date Out of EAB: SEP 30 1987

To: Dick Mountfort
Product Manager 23
Registration Division (TS-767)

From: Carolyn K. Offutt, Chief *Carolyn K. Offutt*
Environmental Processes and Guidelines Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached, please find the EAB review of...

Reg./File # : 100-587
Chemical Name: Metolachlor
Type Product : Herbicide
Product Name : Dual
Company Name : Ciba-Geigy
Purpose : Review of two protocols - one for ground
water monitoring and one for surface water monitoring

Action Code: 177 EAB #(s) : 70163
Date Received: 1/5/87
Date Completed: 9/30/87 Reviewing Time: 10.0

Monitoring study requested: x

Monitoring study voluntarily submitted:

Deferrals To:

 Ecological Effects Branch
 Residue Chemistry Branch
 Toxicology Branch

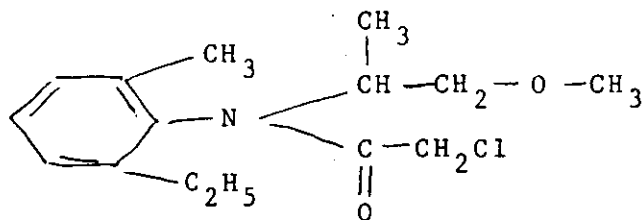
EVALUATION OF GROUND WATER MONITORING PROTOCOL

1. CHEMICAL:

Chemical name: 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide

Common name: Metolachlor

Structure:



2. TEST MATERIAL:

Not applicable.

3. STUDY/ACTION TYPE:

An evaluation of a ground water monitoring protocol.

4. STUDY IDENTIFICATION:

Title: letter from Karen Stumpf to Richard Mountfort and attached protocol entitled, "Protocol: Monitoring Domestic Supply Wells for Metolachlor"

Author: Roux Associates, Inc.
11 Stewart Avenue
Huntington, New York 11743
prepared for:

CIBA-GEIGY Corporation
P.O. Box 18300
Greensboro, North Carolina 27419

Identifying No: 100-587

Submitted by: Karen Stumpf

Report Date: May, 1986

Accession No: not given

Record No: 187308

Pack No: 19769

5. REVIEWED BY:

Matthew N. Lorber, Agricultural Engineer *Mat N. Lorber* Date 7/13/87
Environmental Processes and Guidelines Section/EAB/HED

6. APPROVED BY:

Carolyn K. Offutt, Chief *Carolyn K. Offutt* Date 9/30/87
Environmental Processes and Guidelines Section/EAB/HED

7. CONCLUSIONS:

The submitted protocol is not acceptable to EAB.

8. RECOMMENDATIONS:

EAB recommends that a new protocol be submitted by CIBA-GEIGY. Comments and guidance contained in this review should be forwarded to CIBA-GEIGY to assist in their protocol development. A time limit of 90 days for submission of revised protocol is suggested. CIBA-GEIGY should submit results from this study for our records.

9. BACKGROUND:

A ground and surface water monitoring requirement was specified in the Metolachlor reregistration guidance package, issued in January, 1987. CIBA-GEIGY had seen a draft version in the fall of 1986 (according to Jim Stone, product team 23), and had submitted this protocol in December 1986 in anticipation of the upcoming requirement for surface and ground water monitoring. This protocol describes the selection of counties, strategy to locate wells, and sampling plans for a ground water survey which was to begin in 1986 and be complete by April 1987.

10. DISCUSSION:

Brief comments will first be made concerning the submitted protocol. This will be followed by a listing of key factors for an acceptable protocol, which the registrant may wish to consider in their resubmission of a protocol.

1) Hydrogeologic Vulnerability:

CIBA-GEIGY has only considered aquifers which are "...defined as having been identified in the literature as being extensive and permeable enough to supply municipal and industrial needs (generally 50 gpm and up)..." (p. 4, Ground-Water Sensitivity Analysis). Similarly, "...only the well normally used for potable supply will be sampled at this time." Both these caveats essentially guaranteed that deep non-impacted wells would be the only ones sampled.

All of the 5 counties selected for sampling from the candidate 19 counties listed on Table A-1, p. A-2, were rated "moderately" vulnerable according to the DRASTIC national ratings done for the National Pesticide Survey; 7 of the counties on the candidate list were rated "high" according to this same rating scheme, but were overlooked for county selection.

Ground water monitoring programs acceptable to the Agency will be designed to monitor "impacted" vulnerable ground water - i.e., water table aquifers, unless they are

obviously saline or otherwise unusable or nonexistent. This intention has obvious impacts on well selection, as will be discussed later when listing key points for an acceptable protocol.

2) Number of wells:

Twenty wells, four for each of five counties, sampled four times is insufficient. A large-scale retrospective monitoring study entails hundreds of samples, perhaps from only two rounds of sampling instead of the four listed here. The key is an acceptably large number of wells, rather than many samples from a smaller number of wells.

These are the major two problems with this proposed study design. Many of the design features of this protocol would be accepted in the new proposal requested from the registrant. The following design features are acceptable:

1) Focus on counties of metolachlor use: The registrant has correctly focused on counties of use. However, they have not provided evidence of use; i.e., county-level sales information typically provided by registrants as evidence of use. For the revised protocol, the registrant should focus on those counties of highest use, and should provide evidence of use. Their plan to confirm that 50% of the sensitive acreage in each selected county is treated with metolachlor is laudable, and would prove to be an important confirmation of high use as evidenced by sales data.

2) Focus on counties of vulnerability: The registrant's method to locate vulnerable counties - overlap of permeable farmed soils and unprotected aquifers where the overlap was greater than 30,000 acres - is unique and appropriate. The same method can be applied in the revised protocol, with the single exception that all aquifers be considered - not only those which are capable of supplying municipal or industrial needs.

3) Number of counties: A sampling of five counties is acceptable. Because the registrant will be asked to sample many more than 20 wells, a smaller number of qualified counties, four, would also be acceptable.

4) Number of wells: Somewhere between 50 and 100 wells per county is acceptable.

5) Selection of wells: Selecting wells only on farms with a verified use of metolachlor is also laudable by the registrant. This should be continued with the revised protocol. It should be noted that the monitoring program required in the FRSTR for Metolachlor is a "focused" large-scale retrospective monitoring study, and as such, calls for a purposive selection of wells

rather than a random, statistical selection of wells. These wells will be tapping aquifers potentially impacted by the use of metolachlor. Recognizing that not all candidate wells (where a "candidate" well is one located near a metolachlor use site) will penetrate impacted portions of the aquifer (i.e., near the surface of the water table), every effort should be made to select those that do penetrate the impacted portions. This means that all wells be considered, including USGS observation wells, irrigation wells, and other non-drinking water wells. As well, drinking water wells that "old", such that information on their depth and construction are unavailable, should be considered since they are more likely to be penetrating the shallow portions of the aquifer. Evidence that "point source" contamination, i.e., spills, backsiphoning from chemigation, etc., may have occurred at the well is grounds to reject the well. Every effort should be made to ascertain the possibility of "point source" contamination for a candidate well prior to selection of the well. This can be achieved with interviews with the well owner.

6) Description of selected wells: The registrant should propose, as part of their protocol, information they plan to gather (if available) for each well sampled. This information includes:

- depth of well
- distance from nearest treated field
- topographically upgradient or downgradient from nearest treated field (i.e., whether downslope or upslope from the treated field).

The registrant should be made aware that the study will be rejected if basic descriptions of the well (well depth and depth of screen, primarily) are unavailable. The purpose of the monitoring program is to evaluate the impact of metolachlor on impacted aquifers in the vicinity of treated fields. If this objective was not met, or information supplied is insufficient to ascertain whether this objective was met, then the study will be rejected.

7) Analytical methods: Please see the review of the surface water protocol for a discussion on analytical methods.

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REVIEW OF METOLACHLOR SURFACE WATER PROTOCOL

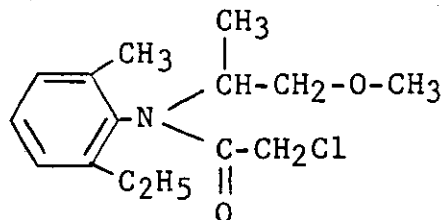
1. CHEMICAL:

Common Name: Metolachlor

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

Trade Name: Metolachlor

Chemical Structure:



2. TEST MATERIAL: Not Given

3. STUDY/ACTION TYPE: Review of surface water monitoring protocol.

4. STUDY IDENTIFICATION: A volume dated December 22, 1986, which included: (I) a "Protocol for Monitoring Surface Water for Metolachlor," dated October 1985, (II) photographs of surface water sites, and (III) Sampling Assistance and Analysis of Metolachlor in Surface Water Samples-Analytical Methods, dated December 8, 1986. This volume was transmitted to R. Mountfort (RD/OPP) from K. Stumpt (Ciba-Geigy Corp.) by a letter dated December 19, 1986. The protocol was prepared for Ciba-Geigy Corp. by Roux Associates, Inc., 11 Stewart Avenue, Huntington, NY 11743.

5. REVIEWED BY:

Harold R. Day
Chemist

Environmental Processes and Guidelines Section 9/30/87

6. APPROVED BY:

Carolyn K. Offutt, Chief
Environmental Processes and Guidelines Section
Exposure Assessment Branch, HED (TS-769)

9/30/87

7. CONCLUSIONS:

This surface water monitoring protocol is provisionally acceptable for measuring metolachlor concentrations in surface water provided the concerns and adjustments listed in 10.D of this review are addressed and resolved.

8. RECOMMENDATIONS:

a. This protocol should be provisionally accepted as valid for determining metolachlor in surface water downstream from treated areas subject to resolution of concerns addressed in Section 10.D of this review.

b. This protocol should have been reviewed before inception of the study. At the very least, registrant representatives should meet with EPA to discuss the protocol. It seems counter-productive and wasteful to review a protocol for a study which has already begun or been completed. This reviewer urges that future protocols be made available for review before a study has begun.

9. BACKGROUND:

On December 9, 1985, Ciba Geigy submitted a Summary of the Metolachlor Water Monitoring Data for 1975-July 1985, as Report No. EIR-85024. The July 15, 1986, review (EAB No. 6189 & 6190) concluded that the usefulness of the data was questionable in the absence of information on "(1) statistical experimental design(s); (2) reasons for selecting water sampling locations; (3) basis for total number of samples; (4) reason for duration and frequency of sampling; (5) precipitation data; and (6) preliminary data on runoff obtained either by monitoring or by predictive surface water modeling (SWRRB, CREAMS, etc)." This submission was followed by a meeting on December 13, 1985, requested by Ciba Geigy representatives. They presented information on monitoring studies voluntarily conducted by the company on atrazine, metolachlor, metalaxyl, and simazine.

Ciba-Geigy has now submitted a protocol for measuring surface water concentrations in areas of metolachlor use. This submission, according to the 12/19/87 cover letter, is in response to requirements of the Draft Metolachlor Registration Standard (no date specified) and contains the same protocol Ciba Geigy has used since late 1985 to monitor for metolachlor in surface water.

This monitoring is a follow-up to data reviewed on 7/15/86 (EAB # 6189, 7/15/86) which provided a summary of metolachlor residues in surface and tap water for the years 1979-1985. It is possible this protocol was submitted in anticipation of data requirements such as those listed in Table A (158.130: Additional Studies, footnote 7, p.53) of the January 1987 Guidance Document for Reregistration of Pesticide Products Containing as the Active Ingredient Metolachlor.

Page 8 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☒ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

The sampling at the gauging stations is by bailer which is rinsed in tap water, distilled water, and finally in water from the sampling location. The collected water samples are composited and a portion placed in a glass bottle, chilled with ice, and shipped Compuchem for analysis. Blank analyses of the rinse water were performed.

The analysis of the samples is by gas chromatography with a nitrogen/phosphorus detector using standard laboratory techniques. Parathion was used as a surrogate for measuring recovery and for checking spiked samples.

B. Results: NA

C. Author's Conclusions: NA

D. Reviewer's Comments and Conclusions:

The following comments are offered on this submitted protocol:

1. The protocol should include, as a minimum, an estimate of the metolachlor use in those counties selected as sampling sites. An estimate of pounds of metolachlor per acre over the county would be best.
 2. A map showing the distributions of metolachlor use in the 102 high use counties, as well as a map of the 61 counties from which the 11 sites were selected.
 3. It is unclear how large a sample is collected at the sampling points selected. Are three gallons collected, or is the composite made up from a larger volume? What volume is extracted as a final sample?
 4. What is the sensitivity of the analytical method? What is the minimum detectible amount?
 5. Why is a nitrogen/phosphorus detector used. Is this more sensitive than electron capture for metolachlor?
 6. There is a need for quality assurance information on the sample extraction and analysis in the low ppb range.
 7. Why is parathion used as a surrogate to check extraction efficiency and spiked samples? Metolachlor, itself, should be used. This is an unacceptable procedure in this reviewer's opinion.
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8. In Appendix A of the protocol, a model of surface water concentration flow is described. According to the data used, metolachlor has a maximum water solubility of 240 mg/l (240 ppm), but literature sources (e.g. Farm Chemicals Handbook), list the solubility as 530 ppm. Why is the former value used and what is its origin?

9. The sampling schedule proposed (12 sampling times through the year) may be insufficient to provide an accurate profile of metolachlor concentrations. If the sampling time is immediately before a rainfall and runoff, the sample will miss the peak metolachlor concentration and could be reported as zero. If this work has already been completed, it is imperative to provide, in the appendix, a history of the sampling in relation to the rainfall events for each site. An analysis and discussion of this rainfall/sampling relationship is also needed.

10. The final report should identify public drinking water supplies in proximity to the 11 sampling sites in order to estimate the population potentially exposed to metolachlor in drinking water.

11. COMPLETION OF ONELINER: NA

12. CBI APPENDIX:NA

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

11/14/11EL
1/5/87

1. CHEMICAL NAME <i>metolachlor</i>			
2. IDENTIFYING NUMBER <i>100-587</i>	3. ACTION CODE <i>177</i>	4. ACCESSION NUMBER <i>-</i>	TO BE COMPLETED BY PM
			5. RECORD NUMBER <i>187306</i>
			6. REFERENCE NUMBER <i>14</i>
			7. DATE RECEIVED (EPA) <i>12/29/86</i>
			8. STATUTORY DUE DATE
			9. PRODUCT MANAGER (PM) // <i>M. Montfort/Stone</i>
			10. PM TEAM NUMBER / <i>23</i>

14. CHECK IF APPLICABLE ☐ Public Health/Quarantine ☐ Minor Use ☐ Substitute Chemical ☐ Part of IPM ☒ Seasonal Concern ☐ Review Requires Less Than 4 Hours		TO BE COMPLETED BY PCB	
		11. DATE SENT TO HED/TSS <i>01-05-87</i>	
		12. PRIORITY NUMBER <i>43</i>	
		13. PROJECTED RETURN DATE <i>03-16-87</i>	

15. INSTRUCTIONS TO REVIEWER A. HED ☒ Total Assessment - 3(c)(5) ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977. B. SPRD (Send Copy of Form to SPRD PM) ☐ Chemical Undergoing Active RPAR Review ☐ Chemical Undergoing Active Registration Standards Review C. ☐ BFSD D. ☐ TSS/RD E. ☐ Other	F. INSTRUCTIONS <i>3/27/87 per some</i> <i>Protocols for surface and groundwater monitoring as recommended by draft metolachlor standard</i> <i>Paul Mustardine was EAB's team member for this standard</i>
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16. RELATED ACTIONS

17. 3(c)(1)(D) ☒ Use Any or All Available Information ☐ Use Only Attached Data ☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.	18. REVIEWS SENT TO ☐ TB ☐ EEB ☐ EF ☐ PL ☐ RCB ☒ EFB ☐ CH ☐ BFSD
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	19. To	TYPE OF REVIEW	NUMBER OF ACTIONS						
			Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE
HED		TOXICOLOGY							
		ECOLOGICAL EFFECTS							
		RESIDUE CHEMISTRY							
	☒	ENVIRONMENTAL <i>EAB</i>	<i>1</i>						
RD/TSS		CHEMISTRY							
		EFFICACY							
		PRECAUTIONARY LABELING							<i>11</i>
BFSD		ECONOMIC ANALYSIS							

20. ☐ Label Submitted with Application Attached	21. ☐ Confidential Statement of Formula	22. ☐ Representative Labels Showing Accepted Uses Attached	23. Date Returned to RD (to be completed by HED)	24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.
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