

CONFIDENTIAL

Shaughnessy No: 090501

Date out of EAB: JUL 2 1987

To: David Giamporcaro
Product Manager
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 #: _____
Chemical Name: Alachlor
Type Product: Herbicide
Product Name: Alachlor
Company Name: Monsanto
Purpose: Review of Monsanto responses to June 18,
1986 data call-in (DCI) Notice for use and exposure data for
alachlor, machine-readable data for surface water protocol
and analytical methods

Action Code: 870 EAB #(s): 70001 and 70002

Date Received: 9/29/86 TAIS Code: _____

Date Completed: 7/2/87 Total Reviewing Time: 30

Monitoring study requested: _____

Monitoring study voluntarily: _____

Deferrals to: _____ Ecological Effects Branch
_____ Residue Chemistry Branch
_____ Toxicology Branch

Revised Dates: 6/29/87, 7/1/87

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1. CHEMICAL:

Common name: Alachlor
Product name: Lasso

2. TEST MATERIAL:

Not applicable: study results were not submitted, although monitoring will be done on raw and finished surface water.

3. STUDY/ACTION TYPE:

Monsanto responses to June 18, 1986 data call-in (DCI) notice for use and exposure data for alachlor - machine-readable data for surface water protocol and analytical methods.

4. STUDY IDENTIFICATION:

Title: "Alachlor Use Information to Support the Surface Water Monitoring Program,"

Submitted by: Monsanto Co. RD 692.

Date: July 14, 1986

Compiled by: S.R. Muench,

Accession #264022

EAB #70002.

Pack No. 17011

and

Title: "Information to Support the Registration of LASSO Herbicides," RD 703.

Submitted by: Monsanto Co.

Date: September 19, 1986

Accession #265133

EAB #70001

Pack No. 19001

5. REVIEWED BY:

Linda L. Kutney
Chemist

Environmental Processes & Guidelines Section Date: 7/2/87

6. APPROVED BY:

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

Carolyn K. Offutt
Date: 7/2/87

7. CONCLUSIONS:

The methods submitted for the separation, identification, quantification, and confirmation of alachlor all appear to be adequate; however, explanation should be given why sample peak areas are not proportional to concentration of sample injected. This information is needed to reach a final approval of the methods included with this submission. The choice of exact method to be used will be left to the analyst.

More lengthy discussion and conclusions concerning the relationships between use, soil type, and alachlor concentrations in surface water are included in the review of "Sampling Locations Selected for the 1986 LASSO Surface Water Monitoring Program."

See CBI appendix.

8. RECOMMENDATIONS:

Monsanto should explain why sample peak areas are not proportional to the reported concentration of alachlor sample injected. Pending receipt of this additional information we can only tentatively conclude that the methods are adequate, based largely on the reported recovery values. The choice of exact method to be used will be left to the analyst.

Recommendations concerning alachlor use, soil type, and alachlor concentration in surface water is included in the review of "Sampling Locations Selected for the 1986 LASSO Surface Water Monitoring Program."

See CBI appendix.

9. BACKGROUND:

A "Special Data Call-In (DCI) Notice for Use and Exposure Data for Alachlor" was sent to Mr. Frank Serdy, Manager of the Monsanto Company on June 18, 1986, i.e., a FIFRA 3(c)(2)(b) letter. These submissions represent Monsanto's response to the DCI notice.

The data were accompanied by ten computer disks which were written in ASCII format. These disks were not compatible with dBase III (as was requested in the DCI Notice) and had to be laboriously translated into dBase III-compatible form, and subsequently reformatted. Much of the data given in the two submissions was identical.

Monsanto has also included, as a DCI response, description of analytical methods for the determination of alachlor. As requested, these methods have not been labeled as CBI.

In response to requirements in the November 1984 Registration Standard on alachlor, Monsanto is being required to submit alachlor surface water monitoring information for 1985 and 1986 in areas of alachlor use. Use data has been submitted for 1984 and 1985. In conjunction with information from other EAB reviews, the data submitted concerning alachlor sales by county will help confirm that monitoring was performed in appropriate locations. It may possibly also help determine the likely national scenario for alachlor concentrations in surface waters.

9. DISCUSSION:

A. ANALYTICAL METHODS

Monsanto submitted analytical methods for the determination and confirmation of alachlor in raw/finished water. As requested in the June 18, 1986, DCI Notice to Monsanto, these methods are not marked as CBI and may be used by community water supply personnel who may want to analyze their water for possible alachlor contamination. Information concerning alachlor use and sales is CBI and is discussed in the attached CBI appendix. The methods are discussed here.

The first method is entitled, "Analytical Method for the Determination of Alachlor in Finished Surface Water Samples." This method involves column chromatography, extraction with 1:9 (v/v) ethyl acetate in iso-octane, drying using Na_2SO_4 , quantitative dilution with iso-octane and analysis by capillary gas chromatography with electron-capture detection (GC/EC). Qualitative identity confirmation by gas chromatography/mass spectrometry (GC/MS) is suggested.

Sample ECD chromatograms provided show clearly where the Alachlor peak should be expected (under the specific instrument conditions). Chromatograms for a 0.1 ppb standard, a 0.5 ppb spike in distilled deionized water, and spikes of 1.0 and 1.7 ppb in contaminated surface water are shown. The areas underneath the chromatograms shown do not appear to be proportional to the sample concentration, as they should be. It is possible that this is due to the exact volume injected,

or to the attenuation setting of the detector. Monsanto should clarify these details in a revised petition; pending the receipt of this information we only give this method tentative approval.

Appendix A to the first method, "Alternative Operating Conditions for Separation and Quantitation of Alachlor Using Capillary GC with Nitrogen-specific Detection," uses a capillary column of different polarity and a Thermionic Specific Detector (TSD) to separate and quantify alachlor. It is less sensitive than the GC/ECD method but may be used to confirm the identity of the alachlor peak when GC/MS is not available. Fortifications of 0.20-25.0 ppb alachlor yielded acceptable average recoveries of 86-111% for the run processed 2/6/86. Again, however, Monsanto should explain why alachlor peaks were not proportional to the concentration of sample injected, as expected.

The third method submitted by Monsanto was, "Analytical Method for the Determination of Alachlor in Raw and Finished Surface Water Samples." This method involves methylene chloride extraction, rotoevaporation, solvent exchange into 5% ethyl acetate iso-octane, drying with sodium sulfate, and dilution to volume with 5% ethyl acetate/iso-octane. Alachlor is separated and quantified with capillary GC/ECD. This sample preparation reportedly is suitable for either confirmatory methodologies submitted by Monsanto. Although recovery values were not given for this method, we tentatively conclude that it is acceptable. Monsanto should validate this method further using spiked samples, and explain why alachlor peaks are not proportional to the concentrations injected.

"Appendix A: Alternative Operating Conditions for Separation and Quantitation of Alachlor Using Capillary GC with Nitrogen-specific Detection" is given again as a possible confirmation for the third method mentioned above, used when mass spectrometry is unavailable. At the 0.2-25.0 ppb fortification level, alachlor recoveries ranged an acceptable 80.0-98.0% for the run processed 1/22/86. Previously Monsanto reported that this method produced average recoveries of 86-111% for the same fortifications (See discussion for for the run processed 2/6/86).

The last method submitted by Monsanto is entitled, "Analytical Method for the Determination of Alachlor in Raw and Finished Surface Water Samples by GC-Mass Spectrometry." Analysis is performed by extraction with methylene chloride, addition of 10% ethyl acetate/iso-octane,

concentration by rotoevaporation, drying with sodium sulfate, and quantitative dilution using a 10.0 ml volumetric flask. Further cleanup is accomplished using reverse-phase column chromatography, eluting with 10% ethyl acetate which is later dried with sodium sulfate. Separation and detection are then accomplished using capillary GC/MS using a selected ion monitoring (SIM) descriptor to monitor ions at m/z 160 and 188 for alachlor and m/z 171 and 199 for the deuterated internal alachlor standard. The deuterated standards elute out first, followed by unlabeled alachlor. The summary report for alachlor analyzed in this way indicates for fortification levels of 0.2-25.0 ppb, average recoveries were found to range between 82.0%-120.5%. This method is the confirmatory method of choice.

When recovery values were given for the above methods they were summarized in this report.

B. SOIL TYPE AND USE DATA

See Confidential Appendix for further, confidential discussion.

11. COMPLETION OF ONE-LINER:

Not applicable.

12. CBI APPENDIX:

Attached.

CONFIDENTIAL CONCLUSIONS

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CONFIDENTIAL CONCLUSIONS AND RECOMMENDATIONS:

The information concerning alachlor sales and estimates of alachlor use for county, state and soil types will be valuable when assessing adequacy of alachlor monitoring sites. It will also be useful in predicting locations where alachlor contamination is likely to occur in surface and/or well water. These data and the computer diskettes should be kept, carefully safeguarded because of their confidential nature, for this purpose.

CONFIDENTIAL DISCUSSION

The most significant information provided on the ten computer diskettes seems to be the estimated quantitation of use (simulated by county sales) in lb/A for counties and states; combined with community water supplies identified by county and state and soil type. Additional information is also given: hydrologic unit, FIPS code, position of the community water supply relative to other hydrological sources, acreage and square-mile area of counties, etc.

Although the sales information is very valuable when assessing whether monitoring sites were properly chosen, the data will not be discussed at length at this time. This data was reviewed along with the information concerning "Sampling Locations for the 1986 LASSO Surface Water Monitoring Program."

Generally high use areas for 1984 and 1985 were the same, occurring, as expected, in mainly the corn-growing and peanut-growing areas. A confidential ranking of the top 100 counties which used alachlor in 1984 and 1985 (based on sales) is attached.

RIN 2858-00

Alachlor EFED Review

Page is not included in this copy.

Pages 8 through 11 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.