

file

Shaughnessy #: 090501

Date out of EAB: DEC 04 1985

Signature: *JM*

To: M. McDevitt
Product Manager # 62
Registration Division (TS-767)

From: Joseph C. Reinert, Chief
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

CCR

Attached please find the EAB review of:

Reg./File No.: _____

Chemical: Alachlor

Type Product: Ferbicide

Product Name: Lasso

Company Name: Mcasanto

Submission Purpose: PD 1, rebuttal

Date In: 4/24/85

Action Code: 827

Date Completed: 4 December 1985

EAB # 5512

Monitoring Requested: _____

TAIS (level II) Days

Monitoring Voluntarily Done _____

7

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

_____ Benefits and Use Division

(1)

SPECIAL REVIEW

REGISTRATION DIVISION DATA REVIEW RECORD

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

HED

1. CHEMICAL NAME

alachlor

#24-85

2. IDENTIFYING NUMBER

090501

3. ACTION CODE

827

4. ACCESSION NUMBER

257523, 257527

TO BE COMPLETED BY PM

5. RECORD NUMBER

149,890

6. REFERENCE NUMBER

7. DATE RECEIVED (EPA)

4/9/85

8. STATUTORY DUE DATE

9. PRODUCT MANAGER (PM)

Derley

10. PM TEAM NUMBER

62

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

4-24-85

12. PRIORITY NUMBER

13. PROJECTED RETURN DATE

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.

- C. ☐ BFSD
D. ☐ TSS/RD
E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)

- ☒ Chemical Undergoing Active BPAR Review
☐ Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

Monsanto submitted toalachlor PD 1.
Please review Table of Contents in Vol. 1.
If there are two volumes you want to see, let me know.

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

19. To

TYPE OF REVIEW

NUMBER OF ACTIONS

Registration

Petition

EUP

SLN

Sec. 18

Inert

MNR. USE

Other

HED

TOXICOLOGY

ECOLOGICAL EFFECTS

RESIDUE CHEMISTRY

ENVIRONMENTAL DATA

Curt Luchik

CHEMISTRY

EFFICACY

PRECAUTIONARY LABELING

BFSD

ECONOMIC ANALYSIS

20. ☐ Label Submitted with Application Attached21. ☐ Confidential Statement of Formula22. ☐ 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.

Monsanto Agricultural Products Company Rebuttal Against The Special Review for Alachlor Pertaining to Aerial Application Exposure
Submitted 9 April 1985

COMMENT: Monsanto submitted an extensive rebuttal to the special review for alachlor on 9 April 1985. One issue raised by Monsanto was that "based on reevaluation of available exposure data, exposure to aerial applicators is considerably lower than previously estimated." Monsanto had previously submitted an exposure study to the Agency (Accession NO. 070591). Monsanto claims in their rebuttal that this study did not accurately reflect the mixing/loading techniques utilized by aerial mixer/loaders, that better estimates are now available for the bulk systems used in the aerial application industry, and that a restriction to mechanical flaggers would eliminate the exposure to flagmen. Monsanto has requested in the rebuttal that EPA reconsider aerial application on the alachlor labels.

RESPONSE: The Agency has investigated the exposure received by workers engaged in the aerial application of alachlor and other pesticides. The exposure assessment is discussed in detail in the nondietary exposure section of the Position Document. The exposure received by flaggers is very variable and produces one of the highest exposures received by any work function. The use of mechanical flagging devices to replace human flaggers would eliminate this source of exposure and is recommended as a label requirement for all alachlor labels should aerial application be reinstated.

The Exposure Assessment Branch has evaluated aerial exposure studies available in the published literature. The purpose of the evaluation was to establish a generic surrogate data base for the application of pesticides. The surrogate data are based on the mixer/loader wearing gloves for hand protection as the only protective clothing worn. Mixer/loaders often use a closed loading system for aerial application operations. Because the alachlor labels do not prohibit open poor loading, exposure estimates for mixer/loaders using either system are presented. A comparison of the exposure estimates based on the Monsanto study and estimates based on the generic data base are presented below. All pilot and flagger exposure estimates are based on the application rate of 3.0 lb a.i./acre used in the Monsanto study.

<u>Job Function</u>	<u>EAB Estimate from Monsanto Data</u>	<u>Generic Data Base Estimates</u>
Mixer/Loader-Open	0.084 mg/lb a.i.	0.95 mg/lb a.i.
Mixer/Loader-Closed	0.0039 mg/lb a.i.	0.023 mg/lb a.i.
Pilot	2.1 mg/hr	2.0 mg/hr
Flagger	113 mg/hr	11 mg/hr

The comparison of the Monsanto data with the surrogate data does not support Monsanto's contention that pilot and mixer/loader exposure was overestimated. Flagger exposure does appear to be overestimated. The Monsanto estimates are based on two replicates while the data base estimates are derived from 20 or more replicates.

The Agency shall reassess the exposure to workers involved in the aerial application of alachlor. One change from the PD-1 will be the change in how mixer/loader exposure is expressed. The PD-1 dealt with mixer/loader exposure expressed in mg/hr. The PD-2/3 will express the exposure in mg per pound active ingredient handled. The latter should be a more accurate indicator of mixer/loader exposure because the time variable is removed.

A second consideration to be evaluated concerning the issue of reinstating aerial application is a comparison of pilot exposure to the alternative, ground boom applicator exposure. Based on an application rate of 3.0 lbs. a.i./acre, pilot exposure is estimated to be 2.0 mg/hr and ground boom applicator exposure is estimated to be 7.8 mg/hr. Annual exposure estimates for pilots and ground applicators will be developed for the PD 2/3.

COMMENT: Monsanto contends that new data demonstrate that applicator exposure to alachlor is two orders of magnitude lower than the PD-1 estimates.

RESPONSE: Monsanto makes the contention for lower alachlor exposures based on data presented in a biological monitoring study conducted after publication of the PD-1. The Exposure Assessment Branch is evaluating worker exposure to alachlor de novo for the PD 2/3.

The nondietary exposure estimates presented in the PD-1 were derived solely from Monsanto supplied data. The exposure studies used Monsanto employees as test subjects and utilized a small number of replicates. The Exposure Assessment Branch has reviewed the published literature and has created an exposure data base for each job function (i.e. ground boom applicator, pilot). The majority of the data bases are based on a relatively large number of replicates (25 to 100) from different studies. The advantage to the data base is that the increased number of replicates presents a clearer picture of the range of exposure that is occurring. This will permit exposure estimates to be based on average exposure and low and high estimates. An example is the review of ground boom applicator exposure. A total of 92 replicates from six studies were evaluated. Based on an application rate of 1.0 lb a.i./acre, the dermal exposure to the applicators ranged from 0.33 mg/hr to 146 mg/hr with an arithmetic mean of 46 mg/hr and a geometric mean of 2.6 mg/hr. This data base allows the estimation of a "typical" exposure of 2.6 mg/hr that would be expected to be as low as 0.33 mg/hr or as high as 146 mg/hr. The range is not unexpected and reflects the variation in personal habits, tractor types, booms, and meteorological conditions that

exists. As comparison, the ground boom applicator dermal exposure estimated from the two Monsanto replicator was 0.15 mg/hr when adjusted to an application rate of 1.0 lb ai./acre. The Agency has used the data base in estimating worker exposure in order to obtain a more accurate picture of the exposures received by American Farmers.

The biological monitoring study submitted by Monsanto has been reviewed by the Exposure Assessment and Toxicology Branches. The study was determined to be scientifically valid and will be utilized in the estimation of nondietary exposure presented in the Position Document 2/3. As Monsanto contends in their rebuttal to the PD-1, a biological monitoring study more accurately reflects the quantity excreted in a given media such as urine. The passive dosimetry (patch) studies estimate the internal dosage by adjusting the estimated quantity of pesticide impinging onto the skin by the percentage of the pesticide that will be absorbed through the skin. Theoretically, both methods should provide the same estimates of dosage. In reality, the correlation between exposure estimates based on passive dosimetry and dosage estimates from biological monitoring studies is low. Franklin, C.A. et al. (1981, Correlation of Urinary Pesticide Metabolite Excretion with Estimated Dermal Contact in the Course of Occupational Exposure to Guthion, J. Toxicol. Environm. Health, 7:715-731) determined that neither linear nor a log-linear correlation existed ($r=-0.4$) between the patched based exposure estimates and 48-hour guthion urinary output. The low correlation may be partially accounted for by failure to account for exposure to unpatched portions of the body.

As demonstrated by the exposure estimates derived from the published literature, exposure to any given individual will vary over a range of expected exposure. Dosage would also be expected to vary over a range for any given application technique. Therefore, the Agency cannot base its risk estimation solely on the Monsanto dosage which was derived from only two replicates per formulation. Both the Monsanto patch exposure and the biological monitoring studies were conducted in Indiana using Monsanto employees. Because both Monsanto studies were conducted under relatively similar conditions and the Monsanto exposure estimate is at the low end of the ground boom exposure range, the Monsanto dosage estimate derived from the urine monitoring study will be used in the PD 2/3 assuming that it represents the low end of a range of dosages expected for ground boom applicators.

Curt Lunchick

Curt Lunchick, Chemist
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (ES-769C)