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Shaughnessy #: 090501

Due Date: 12/26

Init: ~~19 DEC 1984~~

To: R. Taylor
Product Manager #25
Registration Division (TS-767C)

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

Attached please find the EAB review of...

Reg./File No.: 524-316

Chemical: Alachlor

Type Product: Herbicide

Product Name: Lasso

Company Name: Monsanto

Submission Purpose: Exposure Assessment Study-Protocol Review

ZBB Code: _____ ACTION CODE: 450

Date In: 12/13/84 EAB # 5103

Date Completed: 12/18/84 TAIS (level II) Days

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Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

18 DEC 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Alachlor(Lasso), EPA Reg. #524-316. Protocol-Lasso Herbicide Application Exposure Study Biological Monitoring 1984 Field and Sample Protocol.

TO: Robert Taylor, PM #25
Registration Division (TS-767C)

TO: Amal Mahfouz, Ph.D.
Section V
Toxicology Branch/HED (TS-769C)

FROM: Curt Lunchick, Chemist
Special Review Section
Exposure Assessment Branch (TS-769C)

THRU: Joseph C. Reinert, Chief
Special Review Section
Exposure Assessment Branch/HED (TS-769C)

The protocol submitted by Monsanto in September 1984 for applicator exposure study No. 84-24-R-1A has been reviewed. The protocol as outlined appears to be sufficient; however, EAB has several recommendations and comments that should be brought to the registrant's attention.

The exposure study is a biological monitoring study rather than a passive dosimetry exposure study. It can not be stated in strong enough terms that the data obtained from this study are useful for determining worker exposure ONLY if adequate pharmacokinetic data on alachlor are available for review by the Toxicology Branch.

EAB recommends that passive dosimetry (gauze patches) be utilized as an exposure measurement technique in biological monitoring studies. This is recommended as an insurance measure should the pharmacokinetic data be determined to be inadequate or invalid. The protocol submitted by Monsanto indicated that the field experiments conducted in Ontario were so amended. The field experiments conducted in Indiana should have been similarly amended.

When passive dosimetry is utilized in a biological monitoring study, EAB recommends that the gauze patches and other collecting

material be placed on subjects who are NOT used for urine collection. In lieu of this procedure caution must be taken to insure that the collecting material not cover large areas of the body. Cotton gloves and forearm bands are examples of collection devices covering large body areas. This caution is stated because these materials will absorb a significant percentage of the test material and therefore prevent its absorption through the skin so that metabolites will not be excreted in the urine in quantities representative of the worker's exposure.

EAB strongly objects to registrants requesting reviews of protocols for studies that have already been conducted. Monsanto submitted the protocols to EPA in September 1984 although the studies were scheduled for completion in June 1984. Recommendations for amendments in the protocol can not possibly be made after the fact, thereby making the protocol review an exercise in futility. It is hoped that in the future Monsanto will submit their protocols prior to study initiation so that recommendations may be incorporated into the protocol. EAB will insure rapid turn around on protocols submitted for review. This will lead to mutually acceptable and benefical studies for both the registrant and Agency.