MEMORANDUM

SUBJECT: Alachlor (090501) – Special Review and Monsanto Response to Registration Standard

FROM: Susan V. Hummel, Chemist
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THRU: Edward Zager, Section Head
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TO: Robert Taylor, PM#25
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RCB has reviewed a number of alachlor data submissions in response to the Alachlor Registration Standard (See list in Attachment 1). In our reviews, a number of deficiencies in the data were noted. These deficiencies have been summarized and updated in our most recent review of alachlor data (S. Hummel, memo of 1/30/87, Accession Nos. 262999, 263002, 263022, 264946; RCB Nos. 1367, 1368, 1369, 1444). This update did not include a discussion of the deficiencies in the animal metabolism data. These deficiencies are discussed in our memo of 11/1/85 (M. Loftus, Accession No. 257285, RCB No. 1009).

Please forward to RCB (Attn: S. Hummel), as soon as possible, all correspondence from RD to the registrant regarding these data submissions. If the registrant has not been informed of all of these deficiencies to date, we request that a letter detailing these deficiencies and including copies of our reviews be sent to the registrant immediately. The registrant should be required to respond within a short period of time (30 days may be appropriate). Many of the deficiencies could be cleared up with the submission of a small amount of additional raw data.
Monsanto's response to the Alachlor data deficiencies will be an important part of the Residue Chemistry discussion for the Alachlor PD4. The National Resources Defense Council (NRDC), in response to the Alachlor PD2/3, has questioned why Monsanto has not already resolved these data deficiencies.

This information is needed ASAP since RD/SRB has requested a due date of 4/26/87 for RCB to respond to the PD2/3 comments and revise dietary exposure estimates (including review of all Residue Chemistry data currently in house).

Attachment I: Table of RCB Memos: Attached to all copies

RDI: EZ: 02/17/87: RDS: 02/17/87
TS-769: RCB: SVH: svh: RM810: CM#2: 02/17/87
Residue data and protocols have been discussed in the following reviews:

January 30, 1987, Susan V. Hummel (SVH) to David Giamporcaro (DG) and Vicky Walters (VW), review of residue data on corn, milo, and peanuts, and corn processing data, Accession Nos. 262999, 263002, 263022, 264946, RCB Nos. 1367, 1368, 1369, 1444.

December 24, 1986, SVH to VW, review of Monsanto protocols for legume and peanut processing studies and waiver for corn processing studies, Accession No. 264946, RCB No. 1443.

May 13, 1986, SVH and Michele L. Loftus (MLL) to VW and Jane Talarico, Changes in conclusions regarding Registration Standard data requirements and dietary exposure estimates based on new information.

May 12, 1986, SVH to VW, Review of Accession No. 260257, RCB No. 448, Monsanto MSL-5165, MSL-3157, Storage Stability Data for Alachlor DEA and HEEA Metabolites (1 year), and Acetochlor MEA metabolites in corn, soybean, and peanut forage (3 years).

April 18, 1986, Michele L. Loftus (MLL) to Robert Taylor (RT), RCB No. 478, Protocol for Field Residue Trials for legumes.

March 17, 1986, SVH to VW, review of Accession No. 260643, RCB No. 452, Monsanto Report MSL-5118, MSL-4534, Residues in corn grain (LOQ 2 ppb).

March 10, 1986, SVH and MLL to Mike McDavit and Gary Burin (GB), review of Accession Nos. 257523 and 257526, RCB No. 942, Monsanto Response to PDL.

February 14, 1986, SVH to VW, review of Accession Nos. 260259 and 260260, RCB No. 284, Monsanto MSL-5158, MSL-4942, MSL-5123, Residues in Soybean Processed Fractions.

January 15, 1986, Francis D. Griffith to Mike McDavit (MM) and RT, Alachlor MTO Report (DEA Metabolites only).

November 1, 1985, MLL to RT and TOX, Accession No. 257285, RCB No. 1009, Monsanto MSL-4613, MSL-3886, MSL-4230, Metabolism in Ruminants and Poultry.
Attachment 1

October 31, 1985, SVH to VW, Accession No. 257274, RCB No. 1063, Monsanto MSL-4622, MSL-3234, Residues in Dry Beans, DEA Metabolites only.

October 31, 1985, SVH to VW, Accession No. 258142, RCB Nos. 1302 and 1303, Monsanto MSL-4774, MSL-4535, Residues in Soybeans, Preemergent Application

October 31, 1985, SVH to VW, Accession No. 257274, RCB Nos. 1000 and 1001, Monsanto MSL-4625, MSL-3980, Residues in Peanuts, Preemergent Application

October 31, 1985, SVH to VW, Accession No. 257284, RCB Nos. 1012 and 1013, Monsanto MSL-4621, MSL-2869, MSL-2873, Residues in Sunflowers, Preemergent Application, DEA metabolites only, Discussion of previously submitted data on corn, postemergent layby application, DEA metabolites only.

October 29, 1985, MLL to VW and GB, Accession No. 257271, RCB Nos. 1006 and 1007. Monsanto MSL-4636, MSL-3603, Residues in Corn grain, forage, stover, soybean grain, forage, hay, hulls, meal, oil.