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CASWELL FILE

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SCIENTIFIC DATA REVIEWS
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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

FROM: Amal Mahfouz, Toxicologist
Section V, Toxicology Branch
Hazard Evaluation Division (TS-769)

THRU: Laurence D. Chitlik, DABT
Section Head, Section V
Toxicology Branch/HED (TS-769)

SUBJECT: Alachlor, Reg. No. #524-316. Upgrading the Classification
of Two Acute Inhalation Studies. CASWELL#11

Amal Mahfouz
JOC 3/3/84
W/B 3/12/84

Recommendations:

The two acute inhalation studies in rats, one with technical alachlor and another with Lasso EC (45% a.i.) should be upgraded to Core-Minimum. Although a large difference is noted between the gravimetric and analytical concentration of alachlor in the inhalation chamber, the upgrading of these studies is based on the fact that the registrant used the best available technique at the present time.

Both studies were performed by Bio/dynamics (BD-81-183 and BD-81-184 respectively) and they were submitted by Monsanto in Report #MSL-2403, R.D. #433, 7/27/82 (Accession #248053).

Discussions:

These studies were previously classified as Core-Supplementary in my review of 6/22/83 because a large difference was noted between the gravimetric concentration and the analytical concentration of the test substance (5x difference for tests with alachlor technical and 10x difference for tests with Lasso EC). This reviewer then concluded that these studies may later be upgraded to Core-Minimum upon the receipt of a reasonable explanation for these differences by the registrant.

In a letter dated December 2, 1983, Monsanto indicated that the large difference between the gravimetric and analytical concentration of the test material is due to the low volatility of alachlor in comparison to the volatility of the solvent used in these studies (monochlorobenzene, MCB). The registrant also stressed that the maximum attainable nominal concentration of alachlor in MCB was 18.6 mg/L. MCB was used to dissolve the technical material because it is also the solvent used in the Lasso formulations. This rationale is acceptable to this reviewer.

Conclusions:

The registrant's explanations concerning the disparity between the gravimetric and analytical concentration are acceptable to this reviewer. The studies were performed according to the best techniques available at the present time.

However, it is also clear that due to the low volatility of the test substance and due to the limitation of the techniques available at the present time, it is not possible to evenly distribute alachlor in the inhalation chamber. Hence, the results of these studies should be always considered with reservations.