

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

NOV 2 1992

> OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 28-Day Dietary Range-Finding Study of Malathion in the

Rat

Tox Chem No. 535 Submission No. S416766 DP Barcode No. D177425 ID No. 057701 Case No. 818961 None MRID No.

TO:

Joanne Edwards, Review Manager, PM 74

Reregistration Branch

Special Review and Reregistration Division (H7508W)

FROM:

Brian Dementi, Ph.D., D.A.B.T.

Review Section III Toxicology Branch I

Brian Dement 8/24/92 90) R. Januar 1/92 10/24/92 (H7509C) Health Effects Division

THRU:

Karen Hamernik, Ph.D. Acting Section Head Review Section III Toxicology Branch I

Health Effects Division (H7509C)

Judith Hauswirth of Jellinek, Schwartz, Connolly and Freshman, Inc. notified the Agency via letter of April 23, 1992 to Mr. Lawrence Schnaubelt, SRRD, of the results of a 28-day dose range-finding study of malathion in the rat. The intent of this study was to facilitate the selection of dose levels of malathion to be employed in the anticipated chronic/oncogenicity study. Not long after the submission of the results of this 28-day study to SRRD, discussions were held between the registrant and Agency personnel in which HED held that the 28-day study was inadequate to the task of guiding dose selection for the long term study. registrant, accordingly, agreed to conduct a 90-day dietary dose range-finding study. This decision is affirmed in the July 31, 1992 letter of Ms. Diane Allemang to Ms. Lois Rossi, wherein SRRD was advised the 90-day study had begun on May 12, 1992, and the inlife portion was described as expected to terminate on August 13, 1992. Toxicology Branch awaits the results of this study in order to participate in dose selection for the two year study. further action is indicated at this time.