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

MAR 8 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Tetramethrin; Supplemental Data to Subchronic Inhalation Studies (Guideline Requirement 82-4) and Mutagenicity Study (Guideline Requirement 84-4); ID #: 069003-010308; Reregistration Case #: 2660

Tox.Chem No.: 844
MRID No.: 429177-01, -02
DP Barcode No.: D195272
Submission No.: S448753

TO: Kathryn Davis, PM #52
Reregistration Branch
Special Review and Reregistration Division (H7508W)

FROM: William Dykstra, Ph.D., Toxicologist
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THRU: Roger Gardner, Section Head, Toxicologist
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Toxicology Branch I *Roger Gardner 2/23/94*
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*KB
3/7/94*

ACTION REQUESTED: The Registrant, Sumitomo Chemical Company, LTD, has submitted supplemental data to address deficiencies in two 90-day subchronic inhalation studies in rats and a mutagenicity study. These studies were previously core-graded "supplementary". Toxicology Branch-I (TB-I) has been requested to review the new supplemental data and determine if the studies can be upgraded.

CONCLUSIONS: MRID 429177-02 has adequately demonstrated that neopynamin has reached the bone marrow in the mutagenicity test on neopynamin measuring chromosomal aberrations in vivo in mouse bone



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marrow cells. The evidence provided which demonstrates this result is two-fold; (1) C¹⁴-neo-pynamin given orally to rats reaches the bone marrow, and (2) clinical signs of toxicity, including death, in the range-finding and main studies in mice clearly shows that systemic toxicity by i.p. administration has occurred and the bone marrow has been penetrated by the test substance. Therefore, the mutagenicity study (MRID 42414403) can be upgraded to core-minimum and acceptable to support reregistration of neo-pynamin.

MRID 429177-01 has been examined by two HED inhalation toxicologists and the new data supports the conclusion that the actual chamber concentrations for the entire duration of both studies, although only measured 2/days/week, are statistically significantly similar with a C.V. of less than 15%, based on daily nominal measurements. Therefore, the two inhalation studies, MRIDs 419950-03 and 420121-01 are upgraded to core-minimum and support the reregistration of neo-pynamin.