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

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MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Tetramethrin; Miscellaneous Data; ID # 06900 3-010308; Reregistration Action.

Tox.Chem No.: 844
MRID No.: 419950-03,-04,-05
HED Project No.: 1-2511
Submission No.: S403229
MRID No.: 420121-01
DP Barcode No.: D169077

TO: Christine Rice, PM # 52
Reregistration Branch
Special Review and Reregistration Division (H7508W)

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THRU: Roger Gardner, Section Head, Toxicologist
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ACTION REQUESTED: Sumitomo Chemical Company has submitted four new toxicology studies to upgrade their data base for the reregistration of tetramethrin. Toxicology Branch (TB-I) has been requested to review these toxicology studies with tetramethrin submitted in support of reregistration.

CONCLUSIONS: Summaries of the new studies are presented below:

82-2 21 Day Dermal Study in Rats with Neo-Pynamin: NOEL = 1000 mg/kg/day (HDT). Doses = 0, 100, 300, and 1000 mg/kg/day in

5/sex/dose in Sprague-Dawley rats. Classification: Core-Minimum Data.

83-3(b) Rabbit Teratology Study with Neo-Pynamin: Developmental NOEL = 420 mg/kg/day (HDT); Maternal NOEL = 100 mg/kg/day, Maternal LEL = 300 mg/kg/day (Effects are decreased body weight gain during dosing and gestation). Doses are 0, 30, 100, 300, and 420 mg/kg/day (nominal HDT = 500 mg/kg/day) during days 7-19 of gestation in 20 inseminated New Zealand White rabbits/dose. Classification: Core-Minimum Data.

82-4 Subchronic (90 days) Inhalation Study in Rats with Neo-Pynamin: NOEL = 20.3 mg/m^3 (LDT) (Although there were 8% and 10% increases in relative liver weight in females and males, respectively, which were also statistically significant, these findings were condidered not sufficient to establish the LDT as a LEL); LEL = 134 mg/m^3 (Effects were increased clinical signs, decreased body weight gain, changes in hematology , clinical chemistries, and urinalysis, gross necropsy findings in the liver, hepatocellular hypertrophy, hyaline droplets in the kidney, and increased absolute and relative liver and kidney weights). Doses = 0, 20.3, 134, or 824 mg/m^3 by inhalation for 6 hours/day, 5 days/week for 13 weeks, plus 3 days into week 14 in 10/sex/dose in Sprague-Dawley rats. Classification: Core-Supplementary Data (Analytical exposure measurement was only conducted 2 days/week, whereas exposure measurement is required on a daily basis). This study can be upgraded to core-minimum if the Registrant can provide an acceptable explanation as to why analytical measurements were not conducted on each inhalation test day for the entire study.

82-4 Subchronic (90 days) Inhalation Study in Rats with Neo-Pynamin (Determination of the No Observed Effect Level): NOEL = 19.8 mg/m^3 (HDT) (Although a 8.7% statistically significant increase in the relative liver weight in females was observed, this finding was not considered sufficient to establish a LEL). Doses = 0, 1.9, 4.4, and 19.8 mg/m^3 by inhalation for 6 hours/day, 5 days/week for $13^{1/2}$ weeks. Classification: Core-Supplementary Data (Analytical exposure measurement was only conducted 2 days/week, whereas exposure measurement is required on a daily basis). This study can be upgraded to core-minimum if the Registrant can provide an acceptable explanation as to why analytical measurements were not conducted on each inhalation test day for the entire study.

DER's for the submitted studies are attached. It can be seen from the DER's and the summaries above that the 21-day dermal toxicity study in rats and the rabbit teratology study are acceptable as core-minimum data and support reregistration of tetramethrin. <u>However, the two 90-day inhalation toxicity studies, although both having a NOEL for toxicity, are only acceptable as core-supplementary data and do not support reregistration</u>. This classification is due to the inadequate procedure of measurement of

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analytical exposure in the chambers on only 2 days/week, rather than on a daily basis as is required in the Guidelines. These studies can be upgraded to core-minimum if the Registrant can provide an acceptable explanation as to why analytical measurements were not conducted on each inhalation test day for the entire study.