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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: ID. No. 001965-00055, Vancide TH Response to Data Call
In

Tox. Chem. No.: 481B
Project No.: S416864
Bar Code No. : 177488

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CONCLUSIONS:

With regard to correspondence forwarded from J.E. Wilson, pertaining to the acceptability of the mouse micronucleus test (MRID 413215-01) for Vancide TH, Tox Branch I has the following comments:

1. The sensitivity of mouse micronucleus test may not be appropriate for this compound based on the observation of both gastrointestinal and non-gastrointestinal symptoms, indicative of toxicity in the high dose animals. The toxicity of the compound would compromise the results in this case.
2. We agree that the demonstration of the transport of the test material to the bone marrow would involve the use of additional procedures (ex: radioactive tracer studies, cell cycle delay).

Tox Branch I recommends that the sponsor not repeat the mouse micronucleus study; however, a more appropriate study needs to be conducted to satisfy the requirement for a Structural Chromosome Aberration Test (84-2(b)). We suggest that either an in vitro study employing an established mammalian cell line (eg, Chinese hamster ovary, CHO; Chinese hamster lung, V79) or primary (cultured) human lymphocytes (both in the presence and absence of an appropriate mammalian metabolic activation system), be conducted to satisfy this requirement.