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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID# 001965-00055, Vancide TH, Response to Antimicrobial  
Data Call In

Tox. Chem. No. 481B  
Project No.: S436977  
Bar Code No.: D189126

FROM: Sheryl K. Reilly, Ph.D. *Sheryl K Reilly 3/17/93*  
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THRU: Melba S. Morrow, D.V.M. *Msm 3/19/93* *K/B 3/25/93*  
Acting Section Head, Review Section II  
Toxicology Branch I  
Health Effects Division (H7509C)

CONCLUSIONS:

In a memorandum dated July 13, 1992, pertaining to the acceptability of the mouse micronucleus test (MRID 413215-01) for Vancide TH, Tox. Branch I concluded that the sensitivity of the mouse micronucleus test was not appropriate for mutagenicity determination of the test compound, based upon symptoms indicative of toxicity in the high dose animals, which would "compromise the results in this case".

Tox. Branch I recommended that the sponsor not repeat the study in the mouse, but instead use an established cell line, such as the Chinese hamster ovary (CHO), Chinese hamster lung (V79), or primary cultured human lymphocytes (in the presence and absence of an appropriate mammalian metabolic activation system, to satisfy the requirements for a Structural Chromosome Aberration Test (84-2(b)).

R. T. Vanderbilt Company, Inc., has submitted a CHO/HGPRT mutation study to satisfy the requirements of 84-2(b). Tox. Branch I has received the study and it is acceptable for review. However, no review is being conducted at this time. (MRID 415448-01)



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