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

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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Subject: Vancide TH (1,3,5, Triethylhexahydro-s-triazine), Rebuttal letter and additional information. Record No S398565
EPA ID# 1965-55

To: James Wilson/ John Lee, PM # 31
Disinfectants Branch
Registration Division (H7505C)

Tox Chem No 481B
Proj No 1-1646

From: Joycelyn E. Stewart, Ph.D. 11/5/91
Acting Head, Section 2
Toxicology Branch I
Health Effects Division (H7509C)

Thru: Karl Baetcke, Ph.D., Chief,
Toxicology Branch I
Health Effects Division (H7509C)
Karl F. Baetcke 11/19/91

Registrant: R.T. Vanderbilt Co, Inc.,
Norwalk, Connecticut 06855

R.T. Vanderbilt Co has responded to Toxicology Branch's review of a mouse micronucleus assay (MRID 41321501) which was classified Unacceptable based on (1) lack of characterization of the chemical as to its identity, purity and stability and (2) because the study did not demonstrate transport of the chemical to the bone marrow cells.

The company reports that the test chemical was Vancide TH Lot M-TH-8K-327 98.56% a.i. Stability information provided indicated that the chemical was stable both under refrigeration and when stored at room temperature for 90 days. Although the actual raw data was not submitted, Toxicology Branch I accepts the registrant's response.

With respect to the registrant's response to the absence of information regarding transport of the chemical to the bone marrow, Dr. Irving Mauer, Toxicology Branch Genetist, has made the following response: the signs of animal toxicity recorded (ruffling, diarrhea, weight loss, distended abdomen, etc.) leading to death at higher doses, can all be referable to severe irritation of the gut by oral administration of a corrosive substance, rather than evidence of "systemic toxicity" leading to the" normal assumption that the test material and/or metabolites were in the

blood circulation". Acknowledging that the bone marrow is indeed a well vascularized tissue, it does not automatically follow that "the material would reach the target bone marrow cells", as suggested by the registrant. That would have to be demonstrated by some indicator, toxic or mutagenic. Other evidence would be radioactive/tracer studies, cell cycle delay, inter alia; results from other toxicity studies, metabolism etc. The study authors reported no compound related changes in p/n ratio. If this is so, then the bone marrow is not being sampled, therefore, the study could be characterized as NO TEST .

Until the registrant can demonstrate that the chemical was transported to the bone marrow, Toxicology Branch I will consider the mouse micronucleus study to be Unacceptable.