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

MEMORANDUM

JAN 7 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Jay Ellenberger (12)
Registration Division (TS-769)

THRU: Orville E. Paynter, Ph.D.
Chief, Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Evaluation of Validated IBT Study No. 8531-08338:
Ninety-Day Oral Feeding Study of SN 49537 (Thidiazuron)
in Beagle Dogs. Tox. Chem. No. 659A

Review of Data:

Ninety-Day Oral, Dogs. Conducted at IBT (IBT No. 8531-08338), June 1, 1976 and submitted by Nor-Am Agricultural Products.

(This study was validated by Dr. Henry Spencer of Toxicology Branch on July 3, 1979 and classified as Valid. It was revalidated on December 31, 1982 by Dynamac Corporation and classified as Supplementary Data on the basis of the following deficiencies:

1) It could not be verified that all required tissues were examined histologically.

2) It could not be verified that a thorough gross examination was conducted.

3) Diet preparation records were not available for weeks 11-13.

4) It could not be verified that animals were observed daily for signs of systemic toxicity.)

Beagle dogs, approximately 5 1/2 months of age, were exposed to technical thidiazuron at dose levels of 0, 100, 300 and 1000 ppm in the diet. Four males and 4 females were used at each dose level. Animals were fed ad libitum for 5 hours each day and food consumption was measured on a weekly basis. Blood and urine samples were collected after 42 and 85 days on test and were analyzed for the following (blood): leukocyte count, erythrocyte count, Hb, Ht, MCV, MCH, MCHC, differential leukocyte count, BUN, glucose, SAP, SGOT, SGPT, (urine), glucose, pH, specific gravity and microscopic elements. After 90 days, animals were anesthetized by i.v. injection of ketamine hydrochloride and pentobarbital and killed by exsanguination.

An unknown number of tissues were examined grossly and microscopically.

Results:

No mortalities were observed at any dose level. Body weight gain of high dose males was less than that of controls (1.5 kg for T-III males vs. 3.1 kg for controls). Female body weights were not affected by treatment and food consumption was similar for all groups in both sexes. Hematology, clinical chemistry and urinalysis were not affected by treatment.

No organ weight differences were observed which could be associated with treatment. The limited records of gross and histological examination revealed no compound-related alterations. Seventeen of the 36 dogs were diagnosed as having roundworm infections.

Core Classification: Supplementary Data. Based on decreased body weight gain in high dose males, the NOEL may be 300 ppm. However, limitations in clinical observations and gross and histopathology preclude the establishment of a NOEL based on this study.

Gary J. Burin 1/6/83

Gary J. Burin, Toxicologist
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1/7/83

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