3/26/82

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EPL

EXPERIMENTAL PATHOLOGY LABORATORIES, INC.

IBT VALIDATION REPORT

(1) CHEMICAL: SN 49 537 (Thidiazuron).

(2) TYPE OF FORMULATION: Technical-CP-503 (100% active ingredient).

(3) CITATION: IBT Project Number 8560-09631 entitled Two-Year Chronic Oral Toxicity Study with SN 49 537 in Albino Rats.

(4) SPONSOR: Nor-Am Agricultrual Products, Inc.

(5) EPA ACCESSION NUMBER and/or Pesticide Petition Number and/or Registration Number for this IBT Report: EPA Registration Number 2139-Eup-23. Registrant Validation report: Information not present.

(6) VALIDATION PERFORMED BY:

EXPERIMENTAL PATHOLOGY LABORATORIES, INC.

Signature: Tom. Bucey

Date: 3/25/82

Signature: N.A.

Date: _____

(7) Based upon findings listed in this Mitre Corporation Validation Report (which included examination of the final test report, microfiched raw data, and/or the SPRD preliminary report and additional information provided by the sponsor), I concur with this validity determination.

Signature: Laurence D Clift

Date: 3/26/82

(8) TOPIC: This study has information pertinent to the discipline of toxicology. Topic: Chronic Feeding and Oncogenicity Study. It relates to the Proposed Guidelines data requirement 163.83-1 and 163.83-2.

(9) CONCLUSION:

_____ VALID

__X__ SUPPLEMENTARY*

_____ INVALID

*New classification based upon evaluation of additional information submitted by the sponsor (see Addendum and Discussion Summary).

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

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MAY 6 1982

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Jay Ellenberger (12)
Registration Division (TS-767)

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

SUBJECT: Review of Validated Thidiazuron Chronic Rat Study
Conducted at IBT (No. 8560-09631)
CASWELL#659A

NOTE: The review of this study was also included in my memo of April 30, 1982. As noted below, it has been validated and classified as Supplementary Data. It has also been core classified as Supplementary Data. In addition to the deficiencies regarding histopathology (discussed in detail in the study validation addendum prepared by EPL), the following items compromise the utility of this study:

1. Poor animal survival (less than 50% for all male groups at 18 months). Therefore, an excessive number of animals did not survive long enough to demonstrate a potential oncogenic response.

2. High dose males were sacrificed approximately two months prior to sacrifice of their control counterparts, making comparison of tumor incidences extremely difficult.

3. Although compound related effects are suggested at 500 ppm, a Maximum Tolerated Dose is not firmly established. High mortality in control animals, a reflection of animal husbandary problems and ubiquitous respiratory disease, make the identification of compound related effects difficult.

Recommendation:

This study is classified as Core Supplementary Data.

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