

US EPA ARCHIVE DOCUMENT

9-17-82

IBT VALIDATION REPORT

002969

- (1) CHEMICAL: Carzol SP (EP-332 HCl Technical).
- (2) TYPE OF FORMULATION: Technical.
- (3) CITATION: IBT No. A 9144.
- (4) SPONSOR: NOR-AM Agricultural Products, Inc.
- (5) EPA ACCESSION NUMBER and/or Pesticide Petition No. and/or Registration No. for this IBT Report: Registration Nos. 2139-99, 9G0476, OF0961, OF0989, 1F1141, 2F1238, 2H010, 3F1419, 5E1550, 7H5161.

(6) VALIDATION PERFORMED BY:

John R. Strange, Ph.D.
Department Director
Dynamac Corporation

Signature: John R. Strange

Date: 14 September 1982

Cipriano Cueto, Ph.D.
Program Manager
Dynamac Corporation

Signature: Cipriano Cueto

Date: 14 September 1982

- (7) Based upon findings listed in this Dynamac Corporation validation report (which included examination of the microfiched raw data, the sponsor validation report, the final test report, and the SPRD preliminary report when available), I concur with this validity determination.

Toxicologist
Toxicology Branch
HED, EPA

Signature: Mary J. Bui

Date: 9/17/82

Section Head
Toxicology Branch
HED, EPA

Signature: Laurence D. Chittick

Date: 9/17/82

- (8) TOPIC: This study has information pertinent to the discipline of toxicology; topic, cholinesterase activity. It relates to the Proposed Guidelines data requirement 163.81-1 and 163.82.

(9) VALIDATION REPORT CONCLUSION:

 . VALID

 X . SUPPLEMENTARY

 . INVALID

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

002969

MEMORANDUM

OCT 4 1982

TO: Dave Van Ormer, Toxicologist
Toxicology Branch
Hazard Evaluation Division (TS-769)

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Evaluation of Validated IBT Study No. A9144; Twenty-eight Day Subacute Oral Cholinesterase Activity Study with Carzol SP (EP-322 HCl Technical) in Female Albino Rats
CASWELL#465B

Recommendation:

It is recommended that this study be classified as Supplementary Data. The NOEL for RBC and plasma ChE appears to be 0.5 mg/kg; a NOEL cannot be established for brain ChE.

Review of Data:

Twenty-eight Day Cholinesterase Study in Female Rats, IBT No. A9144, February 5, 1971 and submitted by Nor-Am Agricultural Products.

(This study was validated on September 15, 1982 by Dynamac Corporation and classified as Supplementary Data on the basis of the following deficiencies:

1. No baseline cholinesterase data
2. No compound preparation records
3. No protocol in the raw data.)

Twenty female Charles River albino rats were administered 0.5 mg/kg of Carzol technical daily for 28 days in a corn oil suspension by gavage. Plasma and RBC cholinesterase were measured prior to compound administration after days 7, 14, 21 and 28. Five animals were sacrificed after days 7, 14, 21 and 28. Observations and necropsy results were neither reported nor present in the raw data. Cholinesterase was measured using the method of Levine et. al.*

*Levine, J.B., Scheidt, R.A., Nelson, V. "An Automated Micro-Determination of Serum Cholinesterase", Automation in Analytical Chemistry (Technican Symposia). New York, 1965, pp. 582-585.

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