



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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum

Subject: Review of Benomyl GLP/Data Audit;
Record No. 208275; RCB No. 3064.

From: Francis B. Suhre, Chemist *Francis B. Suhre*
Special Registration Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Through: Edward Zager, Section Head *E. Zager*
Special Registration Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

To: L. Rossi, PM-21
Herbicide and Fungicide Branch
Registration Division (TS-767)

RD has requested RCB review and comment on a GLP/DATA Audit of E.I. Dupont De Nemours and Co., Inc. The GLP portion of the audit was conducted by John W. Smith, Inspector, EPA Region III, Philadelphia, PA.; the data portion of the audit was conducted by Dr. Willa Garner, EPA, National Laboratory Audit Program, Washington D.C.

GLP AUDIT

J. Smith's report for the GLP portion of the Audit, identifies and/or describes: the laboratory facility, date of inspection, contact person, studies to be audited, and inspection team.

In his summary statement he states, "...this laboratory is properly equipped and staffed to support the type of data audit at this time. However, equipment maintenance and calibration logs were not available at all pieces of equipment. Standard Operating Procedures (SOPs) Manuals could not be located at a number of stations."

RCB's Comments

Based on the information submitted, we agree with this conclusion.

DATA AUDIT

Data selected for audit were taken from the benomyl metabolism studies listed below:

1. Metabolism of 2-¹⁴C-Benomyl in the Lactating Nanny Goat (A097791).
2. Metabolism of 2-¹⁴C-Benomyl in the Lactating Nanny Goat (Supplement I), (A099097).
3. Metabolism of 2-¹⁴C-Benomyl in the Goat (Supplement II), (A099534).
4. Attempts to Characterize Liver Residues in ¹⁴C-Benomyl Dosed Goat (A070833).
5. Study of Metabolites of Benomyl in Animal Feeding tests (A117467).
6. Determination of Residues of Benomyl and/or Metabolites in Cow Milk, Tissues, Urine, and Feces (A116795).

Several deficiencies involving data calculations, data entry in laboratory notebooks, preparation of dose capsule, and study documentation were cited.

Based on her audit, Dr. Garnder made 4 recommendations, which are restated below for convenience:

1. Since there are 4 ongoing metabolism studies to fill data gaps under Data Call-In, Dupont should be reaudited in late January 1986 or as soon as the studies are submitted.
2. Periodically check components of certified diets used in feeding studies. They (Dupont) said they do this in toxicology studies.
3. They (Dupont) should plan for computer backup, needed in cases of power outages, as they move to computerize all there data gathering activities.
4. On the TLC plates - the radioactive tissue extracts should be mixed and spotted with the cold standards to make sure they co-chromatograph. Side by side is not good enough to prove like R_f values, especially if there is any tailing due to overloading, lipids in the extract, etc.

RCB's Comments

Based on the information submitted, we agree with these recommendations.

cc: R.F., Benomyl S.F., Circu., Reviewer, PMSD/ISB.
RDI:EZ:12/14 /87:RDS:12/14/87
TS-769:RCB:FBS:fbs:557-1883:CM#2:RM814:12/14/87