PMSD/JSB

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

MAY 15 1988

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Response to Questions Regarding Residue Chemistry Data Requirements Listed in the Dichlorvos (DDVP) Registration Standard (RD ID No. 0054810, RD Record No. 219493, RCB No. 3636).

FROM: Debra F. Edwards, Ph.D.
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THROUGH: Charles L. Trichilo, Ph.D., Chief
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Hazard Evaluation Division (TS-769C)

TO: George LaRocca (PM 15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Introduction:

On behalf of the Amvac Chemical Corp., the firm of Jellinek, Schwartz, Connolly, and Freshman, Inc. has submitted a letter, dated 3/31/88, listing several questions pertaining to the residue chemistry data requirements in the dichlorvos (DDVP) Registration Standard, issued in September 1987. These questions pertain specifically to data requirements for animal (livestock) metabolism, storage stability, and residue data for bulk-stored raw agricultural commodities and food handling establishments. Each question will be answered individually.

Questions Regarding the Nature of the Residue (Metabolism) in Livestock:

Question #1: "The Registration Standard asks for Nature of Residue studies to be performed in cattle, swine, and poultry. We have consulted with several laboratories whose consensus opinion is that 14C studies are rarely required on large animals. If we must test cattle and swine, we would like to know if we could perform the cattle and swine studies with non-radio-labeled material."

RCB Response:

Ordinarily, when registered uses of a pesticide include direct treatment of livestock, metabolism studies reflecting such use

are required for each species on which use is permitted. However, in the DDVP Guidance Document (9/87) we required direct animal treatment metabolism data only for cattle, poultry and swine even though direct use is registered on cattle, goats, horses, sheep, swine and poultry. In this case, RCB feels that the data for cattle will permit an adequate determination of the nature of the residue in goats, horses and sheep.

"Nature of the residue" or metabolism studies are required in part to identify the major components of the terminal residue and to show the efficiency of extraction procedures for various components of the residue. Such information can usually be obtained only by the use of radiolabeled material. Therefore, the use of non-radiolabeled material is not acceptable.

Question #2:

"The Standard says that these studies must be performed by "directly treating" cattle, swine, and poultry. What does this mean?"

RCB Response:

Registered uses of DDVP include direct dermal applications. The required metabolism studies using radiolabeled material must reflect these uses.

Question #3:

"In order to develop a protocol, we would appreciate some initial guidance from the Agency. For instance, what size and type of cow should be used?"

RCB Response:

Any common commercial dairy breed will suffice.

Question #4:

"Is the goat metabolism protocol an appropriate model for developing these protocols?"

RCB Response:

RCB has not been provided with a copy of "the goat metabolism protocol." However, RCB recommends that the Registrant submit specific protocols for all required metabolism studies.

Question #5:

"If the metabolism studies need to be performed through dermal application, would EPA consider substituting dermal penetration

studies in cows and pigs in order to assess the amount of absorption and if appropriate, the need for dermal metabolism studies?"

RCB Response:

If the eggs, milk, meat, fat, kidney and liver of cattle, swine and poultry sacrificed within 24 hours of the last of at least three daily dermal direct treatments of [ethyl-1-^{14}C]DDVP applied at an exaggerated rate ($\geq$3x) contain no measurable ^{14}C-residues (^{14}C-detection limit must be $\leq$0.01 ppm), then no additional data will be required. It should be noted that dermally treated animals should be restrained so that oral exposure due to grooming is minimized.

Questions Regarding Storage Stability:

Question #1:

"The text of the Registration Standard is discontinuous. Footnotes 4 and 5 of Table A deal with storage stability: however, the standard jumps from footnote 4 to 6 (pages 87 and 88). Please provide us with the missing text."

RCB Response:

Footnote #5 begins at the top of p. 78. The missing text is as follows:

"All residue data requested in this Standard must be accompanied by data regarding storage length and conditions . . . "

Question #2:

"If Amvac does not defend the crop uses of DDVP, will it be necessary to perform the storage stability analysis with "weathered residue" samples? Because no commodities with weathered residues would be involved, we believe this information would be unnecessary."

RCB Response:

If no crop uses of DDVP are retained, storage stability studies using "weathered residue" samples are not required. Storage stability data generated from fortified samples will be sufficient.

Question regarding Bulk-Stored Raw Commodities:

"According to the residue Science Chapter for testing "bulk-stored raw commodities," only the ULV application with an FC or PrL formulation to exposed bulk-stored peanuts is required. The

standard specifies an SC/L formulation on cocoa beans, wheat, corn, nuts, peanuts and soybeans. A discrepancy exists in both the required formulation and the required test commodities."

RCB Response:

The use information in the Residue Chemistry Science Chapter was incorrect. There is no label requirement to cover or remove commodities during ULV or fog applications of the 5% SC/L. Therefore, data are needed for bulk stored raw agricultural commodities treated via ULV application of the 5% SC/L at 100 g ai/50,000 cu. ft. as specified in the Guidance Document (9/87), rather than for peanuts only at 28 g ai/50,000 cu. ft. as specified in the Science Chapter.

Question Regarding Food Handling Establishments:

"According to the "food-handling establishments" section of the residue Science Chapter, food manufacturing establishments must be treated via space treatment (SC/L) and resin strips; however, the standard indicates only treatment with an SC/L formulation. We need clarification of this issue."

RCB Response:

After the Science Chapter was issued, RCB was informed by the Product Manager (G. LaRocca) that use of resin strips in food handling areas of food manufacturing establishments is not permitted. Therefore, requirements for resin strip treatment were deleted from the data gap in the Guidance Document (Standard).

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cc: Anita Schmidt(SRB/RD), Esther Saito(SIPS/HED), B.Suhre(RCB), PMSD/ISB, RF, SF, Reg. Standards File, Circu, Reviewer

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