

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JAN 25 1990

MEMORANDUM

SUBJECT:

Blufette Dichlorovos (DDVP) Registration Standard

FROM:

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Reregistration Section

Dietary Exposure Branch

(H7509C) Health Effects Division

THRU:

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TO:

J. Talarico

Team-74

Reregistration Branch

Special Review

and Reregistration Division (H7509C)

and

R. Engler, Chief

Science Analysis and Coordination Board

Health Effects Division (H7509C)

Amvac Chemical Corporation has submitted a letter in which they have asked for clarification of several data requirements in the DDVP Guidance Document/Residue and Product Chemistry chapters. These questions and our replies are discussed below.

1) Is Protocol IV testing necessary for DDVP?

DEB's Comment to 1

The Registrant does not have to obtain protocol IV data. Data will be required starting at Protocol C (See PAM 1, Appendix II, revised 4/89) for DDVP.

- 2) Are the data requirements for ultra-low volume application of DDVP to exposed bulk stored peanuts accurate?
- 3) The Registrant proposes to delete data on coffee beans from the list of exposed bulk commodities to be treated.
- 4) The Registrant also proposes to treat the commodities above at a rate of 100 g.a.i. per 50,000 ft³ of head space.

DEB's Comments to 2, 3 and 4

The Guidance Document is accurate. The Branch has no objections to omitting coffee beans as long as data for all of the other commodities is provided. If the maximum application rate reflects treatment of head space volume only, and if this is clearly stated on the lable, then data reflecting this use is acceptable.

5) The Registrant proposes treating bagged commodities at $100 \text{ g.a.i./}50,000 \text{ ft}^3$ as well doing as a timed residue sampling study in place of sampling 6 hrs. post-treatment.

DEB'S Comments to 5

- If 100 g.a.i./50,000 ft is the maximum rate for treating bagged commodities residue data should reflect this use. Samples should be taken starting at 6 hours post treatment and at periodic intervals until a maximum and/or plateau residue level is attained.
- 6) Is requirement for data on processed commodities from treated r.a.c.'s accurate? If so, the Registrant proposes to omit all field crop uses and therefore wishes to omit a tomato processing study. The Registrant further wishes confirmation of requirements for data on cooked meat, eggs and pasteurized milk.

DEB's Comment on 6

The Guidance Document is correct. If there is no remaining use on tomatoes no processing study is required. Data on cooked meat, eggs and pasteurized milk was required due to dietary considerations (i.e., anticipated residues), however, due to the conclusions reached in a dietary exposure assessment for DDVP (See memo of 9/22/88, F.B. Suhre.) this information is no longer required.

7) Are metabolism studies on direct treatment (dermal uses) of cattle, poultry and swine needed?

- 8) The Registrant proposes to do dietary metabolism studies on goats rather than cattle.
- 9) The Registrant questions whether swine metabolism studies (oral and dermal) would be required if the metabolism from both types of

medications is similar in poultry and ruminants and asks that the requirements for metabolism studies on swine be reserved until the results for the poultry and ruminant studies are available.

DEB's Comments to 7, 8 and 9

Metabolism studies reflecting dermal treatment <u>are</u> required. Dietary metabolism studies on goats rather than cattle are acceptable. The Branch has no objection to reserving the need for dermal and dietary metabolism studies on swine until the results of the poultry and ruminant studies are available. If these studies indicate different metabolic pathway for DDVP in different species then the swine studies will be required.

cc: DDVP Reregistration Standard File, DDVP SF, RBP, Circ, TOX, FOD(J.Burrell), P.Fenner-Crisp (HED)

HED: (H7509C):CM#2:X77484:R.B.Perfetti:vg:1/24/90
RDI:R.P.Perfetti, 1/23/90

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