

US EPA ARCHIVE DOCUMENT

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Response to the Residue Chemistry Chapter of the DDVP Registration Standard; Request for Time Extension for Livestock Metabolism Studies (dated 4/16/90). No MRID No., CBRS # 7110.

From: Freshteh Toghrol Ph.D., Chemist *F. Toghrol*
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THRU: Francis B. Suhre, Section Head *Francis B. Suhre*
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To: J. Talarico, PM-47
Reregistration Branch
Special Review and Reregistration Division (H7508C)

In response to the DDVP Registration Standard Jellinek, Schwartz, Connolly and Freshman, Inc. (JSCF) is requesting (letter dated 4/16/90) a number of time extensions on behalf of the Amvac Chemical Corporation. They propose protocol submission dates and request time extensions until 18 month following Agency approval of their protocols. They previously requested clarification of live stock metabolism requirements, stored food and food handling establishment data requirements in JSCF letter of 3/31/88 which was reviewed in our memo of 5/15/88 (D. Edwards, RCB No. 3636).

Livestock Metabolism Studies (Dermal Treatment)

Livestock metabolism studies were received reflecting direct dermal treatment, with consecutive 18-month periods to conduct a

goat metabolism study followed by the hen metabolism study. This letter was accompanied by protocols dated 7/3/90. CBRS has already reviewed the submitted protocols (see W. J. Hazel, memo dated 8/14/90).

CBRS Comments:

The time extension request for pending livestock metabolism studies is not scientifically justified, the petitioner should submit data on livestock metabolism eighteen months after the effective date of the DCI.

Bulk Stored Commodities, Bulk Bagged Commodities, and Related Bagged Commodities:

The registrant's agent (JSCF) indicates that protocols for these studies will be submitted by 10/1/90 and requests a time extension until 18 months after Agency approval of the protocols.

JSCF state that extensive research was required to determine the worst case scenarios for DDVP Residues Stored Commodities, because of the many varied uses of DDVP and that JSCF need to do further research to determine the most efficient approach to analyzing residues in a diverse group of commodities packaged in a variety of different ways. JSCF also cite problems with the volatility of DDVP and laboratory inexperience.

CBRS Comments:

We have no record of submission of protocol for stored commodities. The variety of uses and laboratory inexperience are not scientifically justified reasons for a time extension.

Food Handling Establishments

The registrant agent JSCF proposed to delay initiation of this study until they can establish the DDVP livestock and commodity testing program (unspecified time extension). They cite the complexity and scope of the DDVP testing programs reasons for the delay.

CBRS Comments:

No specific justification has been provided. Sufficient time was allowed in the DDVP Registration Standard for this study the required testing program was outlined in the Registration Standard. Additional guidance may be found in the Residue Chemistry Guidelines.

Meat, Milk, Poultry, and Eggs (Dermal Application):

The registrant agent JSCF proposed to delay initiation of this study until they can establish the DDVP livestock and commodity testing program (unspecified time extension). They cite the complexity and scope of the DDVP testing programs reasons for the delay.

CBRS Comments:

Although not stated as a reason for a time extension, the result of the livestock metabolism studies are needed in order to conduct a residue study (dermal application). A time extension of 12 to 18 month following the due date of the livestock metabolism studies would be justified.

CBRS Conclusions:

The time extension requests for studies on livestock metabolism studies; residue studies on bulk stored commodities; bulk bagged commodities, and retail bagged commodities; and residue studies for food handling establishments are not scientifically justified. A time extension of 12 to 18 months would be appropriate for the residue studies on meat, milk, poultry and eggs (dermal application) would be appropriate.

CBRS recognizes that this is an administrative decision and defers the issuance of the time extension request to the Reregistration Division.

cc: DDVP S.F., R.F., Reg. Std., Circ., F. Toghrol, PMSD/ISB.
RDI: S.H 2/15/91): E. Zager: (2/19/91):
H7509C:DEB:F.Toghrol:F.T.:RM:802:CM#2:703-557-7887:2/20/91.