



Department of Pesticide Regulation



Mary-Ann Warmerdam
Director

MEMORANDUM

Arnold Schwarzenegger
Governor

TO: Joseph Frank, Senior Toxicologist
Worker Health and Safety Branch **HSM-07001**

FROM: Michael Dong, Staff Toxicologist (Specialist) *(original signed by M. Dong)*
Worker Health and Safety Branch
(916) 445-4263

DATE: March 6, 2007

SUBJECT: RESPONSE TO REQUEST BY AMVAC FOR AN EXEMPTION FROM
CONDUCTING THE AIR MONITORING CLOSET STUDY ON DDVP -
REGISTRATION EVALUATION PACKAGE ID# 219483

Summary: This memorandum is submitted in response to a request by AMVAC for an exemption from conducting the air monitoring closet study on DDVP. The conduct of such a study was part of the 2001 Stipulated Order and Final Decision entered into between all of the current DDVP registrants, including AMVAC, and the Department of Pesticide Regulation (DPR) (DPR, 2001; Woods, 2001). This final decision, as well as the need for the study submission, was entered for the purpose of resolving issues on DPR's action to cancel the DDVP pest strip products used in California on the grounds that they are detrimental to public health and safety.

We scientists at the Worker Health and Safety (WHS) Branch consider the closet study necessary for several reasons. The data were requested to validate assumptions used in the exposure estimations and to address a lack of suitable real time data on DDVP air concentrations in treated areas and their adjacent rooms. At the time of DPR's assessment of DDVP, the only air monitoring data available were from a 1973 study conducted by Collins and DeVries (1973). While relying on this study for our exposure assessment, we considered the study inadequate to fully address exposure potential. The monitoring was conducted in homes with variables and conditions that would not be expected to capture upper-bound exposures. Furthermore, the older homes as used in the study are not representative of modern structures. Due to improved insulation and air circulation control, modern structures are believed to have a higher potential for buildup of air contaminants than older structures. We believe that these deficiencies may lead to an underestimate of potential residential exposure. Based on the available information, we are unable to quantify this potential underestimate without adequate empirical data.

AMVAC has presented several arguments in support of their request of an exemption. Their primary argument is that the highest acute air concentration encountered by residents should be 0.1 mg/m^3 per 1,000 cubic feet. The problem is that their estimate was derived from the air monitoring data presented in the same 1973 Collins and DeVries study that WHS scientists found inadequate.



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The registrant (AMVAC) also proposed reference concentration and margin of exposure approaches that differ from those presented in DPR's Risk Characterization Document (RCD) (DPR, 1996). In consideration of their proposal, Scientists at the Medical Toxicology (MT) Branch conducted a preliminary evaluation of the currently available toxicity information. On the basis of this evaluation, it was concluded that the insignificant risk interpretation of the registrant was not supported. While we consider the registrant's proposal to reduce the size of the pest strips a mitigation effort, the impact of such a proposal cannot be determined without monitoring data.

We scientists at WHS recommend that AMVAC's exemption request be denied and that the monitoring study at issue be conducted and submitted as soon as possible. Furthermore, we recommend that the new label language for the new 16-gram pest strip product not be approved for registration, as it does not include the use restriction for places where infants, children, and the sick or aged are or will be present for any extensive period of confinement.

Background: On February 22, 2001, as pursuant to California Administrative Procedure Act section 11517(b)(2)(A), DPR adopted the February 13, 2001 Stipulated Final Order (of the Office of Administrative Hearings), in its entirety, as a final decision in the matter of cancellation of the registration of the DDVP (dichlorvos) pest strip products.

The Stipulated Final Order, that was signed by all relevant parties including the registrants, was entered into for the purpose of resolving issues raised in the accusations filed for the above cancellation matter. According to paragraph 3 in that Order, the registrants had agreed to submit within 180 days, from February 13, 2001, further pest strip monitoring data, other information, and/or protocols for conducting a study to further support (or expand) the uses of pest strips allowed at homes. The registrants had further agreed to confer with DPR on any study protocols and time frames for data submission, and to initiate a study within 6 months of the protocol being agreed upon by both DPR and the registrants.

Pursuant to the above stipulation, AMVAC submitted on July 25, 2003 their draft protocol (Protocol No. PRS02001, Rev. Jul-03) for the study entitled "*Indoor Air Concentrations of DDVP Using Pest Strips in Confined and Unoccupied Areas.*" That protocol was reviewed by DPR through its Registration Tracking No. 201549. Since the adoption of the Final Decision, there have been no further relevant air monitoring data on pest strips or other relevant information available to further support the uses allowed under the Stipulated Order. The need for the submission of the closet study was justified in the review of the draft protocol (Dong, 2004).

AMVAC's Request: Below are WHS scientific staff's responses to AMVAC's exemption request, which was submitted for review through DPR's Registration Tracking No. 219483.

1. AMVAC reported that they are currently in the process of replacing the 21-gram pest strip with a new 16-gram strip for use in closets. They indicated in their risk assessment calculations that this reduction in strip size would reduce the potential exposure by approximately 25%.

We agree that the use of a new 16-gram pest strip in closets could amount to approximately a 25% reduction in potential exposure. However, we consider this percentage of reduction inconsequential compared to the exposures of concern (i.e., primarily those for children and elderly residents).

While the proposed reduction to the 16-gram strip reduces the air concentration in the closet itself, it does not necessarily reduce bedroom exposure. The (proposed) label language for the 5.25-, 10.5-, and the new 16-gram pest strips now reads: “*Within homes, use only in closets, wardrobes, and cupboards. Also for use in storage units, garages, attics, . . .*” Therefore, as written the new label language does not *explicitly* preclude homeowners from using more than one of these pest strips in a bedroom at any given time. For example, according to the new label language, homeowners each may use a 5.25-gram strip in a cabinet, a 5.25- or 10.5-gram strip around a rolling garment rack (for wardrobes), *and* a 16-gram strip in a closet, *all* within a master bedroom. The new label language also does not include the use restriction for places where infants, children, and the sick or aged are or will be present for any extensive period of confinement.

2. AMVAC based their risk assessment for inhalation exposure on the reference concentration of 27 $\mu\text{g}/\text{m}^3/\text{day}$ derived by U.S. Environmental Protection Agency (using BMDL₁₀ of 800 $\mu\text{g}/\text{kg}/\text{day}$ from an oral toxicity study in rats and uncertainty factor of 30). In its existing RCD, DPR used a reference concentration of 3.25 $\mu\text{g}/\text{m}^3/\text{day}$ (based on a NOEL of 325 $\mu\text{g}/\text{kg}/\text{day}$ as absorbed dose and uncertainty factor of 100) from an inhalation toxicity study in rats. DPR considered inhalation toxicity study data as more appropriate to address inhalation exposure. As of this date, no additional inhalation toxicity studies have been submitted to DPR. The preliminary re-evaluation of the currently available data by the MT Branch does not support the use of the oral study for inhalation exposure.
3. AMVAC assumed that the highest acute air concentration encountered by residents would be 0.1 mg/m^3 per 1,000 cubic feet. With this and previously discussed assumptions, AMVAC estimated that residential exposure to DDVP was acceptable.

The basis for AMVAC’s estimate was the air monitoring data presented in Collins and DeVries (1973). In that study, air concentrations ranging from 0.03 to 0.12 mg/m^3 per 1,000 cubic feet per strip were observed at day 1 in the 15 homes treated with DDVP pest strips (presumably of 65 or 80 grams each).

We scientists at WHS continue to have concerns with the use of those data since they did not include homes constructed more recently. Many homes built today are deemed to be more energy-efficient and hence more airtight than those built over three decades ago. It was due to this concern that we stipulated that the closet study should include all homes less than 10 years of age. Furthermore, to reduce the possibility of underestimating potential exposure and to decrease confounding variability, we stipulated that the studies should be conducted such that during the sampling period, doors to adjacent rooms should be closed, the rooms should not be air-conditioned, fanned, or heated, and the windows should not be opened. We also indicated that a human exposure study was not needed nor desired. We believe that uncontrolled movement in the monitoring area would likely reduce exposure estimates and increase uncertainty in estimating potential acute exposure. Since closets doors can be left open, and closets may also have louvers or other openings allowing movement of air to adjacent bedrooms, a monitoring study should also address the potential impact of bedroom air concentrations with closet doors open and closed. The out-of-date air monitoring study conducted by Collins and DeVries (1973) did not include such considerations.

References

- Collins RD, DeVries DM, 1973. Air Concentrations and Food Residues from Use of Shell's No-Pest[®] Insecticide Strip. *Bull Environ Contam Toxicol*, 9:227-233.
- Dong MH, 2004. Review of AMVAC's Study Protocol for DDVP Pest Strips, Registration Tracking ID #201549. Worker Health and Safety Branch, Cal/EPA Department of Pesticide Regulation, dated March 15.
- DPR (California Department of Pesticide Regulation), 2001. Final Decision: In the Matter of Cancellation of the Registration of Pesticides Containing Dichlorvos, signed by Director Paul Helliker on February 22, 2001.
- DPR, (California Department of Pesticide Regulation), 1996. Dichlorvos (DDVP) - Risk Characterization Document. Medical Toxicology Branch, Cal/EPA Department of Pesticide Regulation.
- Wood JC, 2001. In the Matter of Cancellation of the Registrations of Pesticides Containing Dichlorvos Against: AMVAC Chemical Corporation; DPR No. 99-001; OAH No. N-200003030422 and Related Matters of Loveland Industries, Inc., and Spectrum Group. (Letter to DPR Deputy Director Paul Gosselin.) AMVAC Chemical Corporation, dated August 20.

cc: Ann Prichard, Agriculture Program Supervisor IV, Registration Branch