DICHLORVOS (DDVP)

MITIGATION PROPOSAL FOR REDUCTION OF HUMAN EXPOSURE

BY

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California Environmental Protection Agency
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EXECUTIVE SUMMARY

DICHLORVOS (DDVP)
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Worker Health and Safety Branch
Department of Pesticide Regulation
California Environmental Protection Agency

BACKGROUND

DDVP is an insecticide that is used in California for pest control in various structures, including livestock and poultry premises, and on livestock, pets, and stored agricultural commodities. The Department of Pesticide Regulation (DPR) prepared a risk characterization document in which human occupational and non-occupational (indoor residential) exposures to DDVP have been estimated and toxicological risks of exposure have been evaluated. The risk assessment concluded that the non-oncogenic margins of exposure (MOE) for most of the exposed occupational and non-occupational categories were less than the generally considered acceptable benchmark (100 or 10 based on animal or human toxicology study, respectively). The excess lifetime oncogenic risks for exposed occupational and non-occupational categories were greater than the benchmark oncogenic risk level of 1×10^{-6}.

This document was prepared to propose mitigation measures, where applicable, to reduce the exposure to a level that would render an MOE of 100 or more for the potentially exposed groups.

PROPOSALS

Occupational Exposure Scenarios:

The exposure to handlers and other workers, such as warehouse workers, livestock applicators, and structural applicators, would have MOEs at or above the benchmark with further mitigation measures. However, when occupational exposure is combined with residential exposure, no practical mitigation measures would result in MOEs at or above the benchmark for this exposure scenario.

The current label prohibits reentry to warehouses 6 hours after the application. A reentry 24 hours after the application allows for DDVP air concentration to drop to a level that would provide an MOE greater than 100 for workers reentering treated warehouses. The reentry into treated warehouses and other enclosed structures should be extended to 24 hours.

All handlers should wear coveralls in addition to work clothing and chemical resistant gloves while mixing, loading and applying, except when handling products with automatic devices. Handlers applying DDVP to livestock and livestock and poultry premises should also wear a half-face respirator when handling inside enclosed areas.

Residential Exposure Scenarios:
With the exception of pest strips, no reasonable and practical mitigation measures would reduce the estimate of indoor DDVP exposure to residents to a level that would provide an acceptable MOE. The use of pest strips in residential areas should be limited to smaller size strips. In addition, pest strips should not be used in rooms occupied by infants, children, elderly, and ill people. On February 22, 2001, DPR reached an agreement with the DDVP registrant on the implementation of the above mitigation measures for the pest strips. These mitigation measures were implemented as label amendments to the pest strip product labels. The use of all other DDVP products in residential and institutional structures where people are expected to be present for an extended period such as homes, offices, hospital, restaurants, motels, and schools should be eliminated.

CONCLUSION
With the prohibition of the most residential and institutional uses, the non-dietary exposure to the general population will be limited. With the proposed mitigation measures, the MOE for acute occupational exposure ranged from 125 to 714 and the MOE for chronic occupational exposure ranged from 109 to 227. The excess lifetime oncogenic risk for occupational exposure ranged from 1.2×10^{-5} to 4.6×10^{-5}.

Mitigation Proposal for Reduction of Human Exposure to
Dichlorvos (DDVP)

January 2002

Introduction

DDVP is an insecticide that is registered in California for use in residential, institutional, and industrial structures (such as homes, schools, warehouses, factories, livestock premises), and on livestock, pets, and stored agricultural commodities. There are several formulations of DDVP-containing products including liquid, aerosol spray, fogger, impregnated strip, and pet collar. DDVP is a volatile insecticide with a vapor pressure of 1.2×10^{-2} Torr @ 20 ^{o}C. The Department of Pesticide Regulation (DPR) prepared an exposure assessment in which human occupational and non-occupational exposures to DDVP were estimated (Fong and Formoli, 1993) and a risk assessment in which toxicological risk of exposure was evaluated (Lim *et al*., 1996). The risk assessment concluded that the margins of exposure (MOE) for non-oncogenic effects for most of the exposed occupational and non-occupational categories were less than the benchmark. The excess lifetime oncogenic risks for exposed occupational and non-occupational categories were greater than the benchmark level of 1×10^{-6} (Lim *et al*., 1996). An MOE is defined as the ratio of no observed effect level (NOEL) in toxicological studies to the estimated exposure dosage. An MOE of 100 or more based on animal toxicology studies is generally considered acceptable. An MOE of 10 or more is generally considered acceptable when it is based on human toxicology studies. With the review of additional toxicology and dietary exposure data, dietary exposures are no longer of concern (Lim, 1998). In addition, route-specific NOELs and MOEs are proposed.

This document was prepared to propose mitigation measures, where applicable, to reduce the exposure and increase the MOE for the potentially exposed groups.

Current Exposure Levels and Risk:
The estimates of exposure in the exposure assessment document were based on DDVP studies, except for livestock applicators where surrogate data were used. The estimates of exposure and the corresponding MOEs for the occupational and non-occupational tasks are shown in Tables 1 and 2. The acute MOEs in Table 1 are route specific. A rabbit inhalation toxicology study was used to calculate MOEs for inhalation exposure. A human acute oral study was used to calculate MOEs for dermal and oral exposure. The exposure categories for which the MOEs (based on animal studies) were less than 100 and the MOEs (based on human studies) were less than 10 are identified with an asterisk, requiring mitigation.

Current Mitigation Measures:
While the uses of DDVP overlap between products, the labels can be grouped into the following six general use categories:

1. Indoor and outdoor residential, institutional, and industrial uses.
2. Stored agricultural commodity uses in warehouses.
3. Livestock, livestock premise, and poultry house uses.
4. Pet collars.
5. Pest strips for residential, institutional, industrial, agricultural commodity warehouse, and livestock premise uses.
6. Aerosol jet sprays for outdoor nuisance insect control.

The worker protection statements on the labels for indoor and outdoor residential, institutional, and industrial uses require a respirator with no statement for dermal protection. The reentry interval to treated warehouses is 6 hours. The worker protection statements on the labels for occupational uses such as livestock, livestock premises, and poultry house applications require workers to wear rubber gloves, water-proof protective clothing, and eye protection when handling the concentrate to prepare emulsions. The statements also require workers to wear a pesticide respirator jointly approved by Mine Safety and Health Administration (MSHA) and National Institute of Occupational Safety and Health (NIOSH). The labels for outdoor uses of long range jet-stream aerosols against nuisance insects such as bees and wasps require handlers to wear long-sleeved shirts, long pants, chemical resistant gloves, socks, and shoes. The label for residential uses requires that children and pets not be allowed to contact treated surfaces until the spray has dried.

Table 1. DDVP Estimates of Occupational and Residential Acute Exposure (µg/kg/day) and MOE Prior to Proposed Mitigation Measures

Exposure Category (formulation)	ADD (µg/kg/day)[a]				MOE			
	Inhalation	Dermal	Oral	Total	Inhalation[b]	Dermal[c]	Oral[c]	Total[b]
Warehouse worker* (aerosol)	12	na	na	12	27	na	na	27
Structural PCO (E.C.)	0.5	8.7	na	9	650	57	na	36
Livestock applicator* (liquid)	55	7	na	62	6	71	na	5
Child* (resin strip)	29-40	na	na	29-40	8-11	Na	na	8
Child* (fogger)	33	85	17	135	10	6	30	3
Adult* (fogger)	32	57	1	90	10	9	500	4
Pet owner (pet collar)	0.3	na	na	0.3	1083	na	na	1083

a - Absorbed daily dosages (ADDs) and their development are reported in the DDVP exposure assessment document (Fong and Formoli, 1993)

b - MOE based on an adjusted NOEL of 325 µg/kg/day for cholinergic signs and mortality observed in a rabbit inhalation study (Lim, 1998). Target MOE is 100 or greater.

c - MOE based on a NOEL of 500 µg/kg/day for RBC cholinesterase inhibition observed in a human acute oral study (Lim, 1998). Target MOE is 10 or greater.

*- Requires mitigation for acute exposure.

na – Not applicable.; E.C. – Emulsifiable concentrate

Table 2. DDVP Estimates of Occupational and Residential Chronic and lifetime Exposure (µg/kg/day) and MOE Prior to Proposed Mitigation Measures

Exposure Category (formulation)	AADD[a] (µg/kg/day)	MOE[b]	Lifetime Oncogenic Risk[c]
Warehouse worker* (aerosol)	0.6	42	6×10^{-5} to 1×10^{-4}
Structural PCO* (E.C.)	0.8	31	8×10^{-5} to 1×10^{-4}
Livestock applicator* (liquid)	4.6	5	5×10^{-4} to 9×10^{-4}
Child* (resin strip)	6.6	4	
Child* (fogger)	2.1	12	
Adult* (fogger)	1.2	20	1×10^{-4} to 2×10^{-4}
Pet owner (pet collar)	0.05	500	6×10^{-6} to 1×10^{-5}

a – AADDs (annual average daily dosages) and their development are reported in the DDVP exposure assessment document (Fong and Formoli, 1993)

b - MOE based on an adjusted NOEL of 25 µg/kg/day for brain ChE inhibition in a rat inhalation study (Lim, 1998). Target MOE is 100 or greater.

c - Oncogenic risk based on potency factors of q1 of 0.0002 µg/kg/day and q1* of 0.00035 µg/kg/day for mononuclear leukemia in rat (Lim, 1998).

*- Requires mitigation for chronic exposure.

Mitigation Adequacy for Various Work Tasks

Exposures Requiring Additional Mitigation:

1. *Workers:*
   Based on the MOE in Table 1 for acute exposure, all listed worker exposure categories, except structural PCOs, require mitigation. Based on the MOE in Table 2 for chronic exposure, all listed worker exposure categories require mitigation.
2. *Residents:*
   Except for residents exposed to pet collars, all other residential exposure categories listed in Tables 1 and 2 require additional mitigation.

Exposure not Requiring Further Mitigation:

The MOE for residents exposed to pet collars is greater than 100. No further mitigation is required.

Mitigation Options

It appears that occupational exposure alone for workers listed in Tables 1 and 2 would have acceptable MOE with further mitigation measures. However, when the exposure from occupational sources are combined with the exposure from residential sources, no practical mitigation measures would result in MOE close to the benchmarks for these workers. Furthermore, with the exception of pest strips, no reasonable and practical mitigation measures would reduce the estimated exposure to residents to a level that would provide an MOE that is generally considered acceptable.

Administrative Controls:

- The estimates of indoor exposure to residents were based on a study that monitored the exposure of human volunteers to DDVP following a fogger application (McDonald, 1991). Biological and dosimetry monitoring as well as air monitoring were conducted to estimate the exposure of volunteers. The estimates of ADD were for children and adults entering treated residences three hours following application. Air monitoring showed DDVP concentration at 50 ug/m^3 even 27 hours following the monitoring. Dosimetry monitoring was not conducted the day following the application to estimate dermal exposure. No reasonable and practical mitigation measures would reduce the estimated exposure to residents to a level that would provide MOE of 100 or greater. In addition, the estimate of ADD for children exposed to DDVP resin strips also resulted in an MOE that was less than 100. See the attachment I for mitigation measures for resin strips. On February 22, 2001, DPR reached an agreement with the DDVP registrant on the implementation of the mitigation measures noted on attachment I.

  The use of DDVP in residential and institutional structures where people are expected to be present for an extended period such as homes, offices, hospitals, restaurants, motels, and schools should be eliminated (see attachment I for resin strips).

- The estimate of exposure for warehouse workers was based on a study in which air concentrations were monitored in a warehouse treated with DDVP (Knight, 1985). The

estimate of exposure was for workers reentering the treated warehouse 12 hours following the application. A 24-hour reentry interval after the application allows for DDVP air concentration to drop to a level that would result in an MOE greater than 100 for workers reentering the warehouse.

The reentry into treated warehouses and other enclosed structures should be extended to 24 hours.

Personal Protective Equipment (PPE):

- Surrogate data were used to estimate the exposure of workers applying DDVP to livestock. The surrogate study estimated exposure for workers using backpack, hand-held, or portable sprayers (Merricks, 1988). Workers wore long-sleeved shirts, long pants, rubber gloves, socks, and shoes. Dermal exposure of workers using backpack sprayers was used as a worst-case scenario to estimate the exposure of applicators applying DDVP to livestock. The dermal exposure to workers using hand-held or portable sprayers was several fold less than those using backpack sprayers. Coveralls could reduce exposure to a level that, along with other PPE requirements (chemical resistant gloves, respirator), would result in an MOE of greater than 100.

  Handlers applying DDVP to livestock and livestock and poultry premises should wear coveralls in addition to work clothing and chemical resistant gloves. They should also wear a half-face respirator when handling inside enclosed areas.

- The MOEs for structural PCOs in Table 1 were 650 for inhalation route and 57 for dermal route. Since the dermal MOE is greater than 10 and based on human toxicology data (see Introduction section) and the inhalation MOE is greater than 100, these MOEs are considered acceptable for acute exposure. However, Table 2 shows that chronic exposure of structural PCOs requires mitigation. The prohibition of indoor residential and institutional structural applications would reduce the frequency of exposure for the PCOs. The estimate of exposure for PCOs in Table 1 is based on a study in which dermal and inhalation exposure of residential structural PCOs was monitored. The estimate of exposure was for workers wearing work clothing and rubber gloves. Most of the dermal exposure occurred to the head and body. Hand exposure under gloves was minor.

  Handlers applying DDVP to structures should wear coveralls in addition to work clothing and chemical resistant gloves.

Mitigation Proposal

- Prohibit all indoor residential and institutional uses (except for pet collars and resin strips).
- See attachment I for mitigation measures for resin strip
- Require a 24-hour reentry interval following use in warehouse and other enclosed structures.
- Require coveralls over work clothing and chemical resistant gloves for all workers while handling DDVP, except for products with automatic application devices for warehouse treatment. Handlers applying DDVP to livestock and livestock and poultry premises should also wear a half-face respirator when handling inside enclosed structures.

Estimate of Exposure Following Proposed Mitigation

By Work Task/Mitigation Option:

- The estimate of exposure for warehouse workers listed in Table 1 is for workers reentering the treated warehouse 12 hours following an application. This estimate was based on a study in which air concentrations were monitored at several intervals in a warehouse treated with DDVP (Knight, 1985). Air samples were taken 1-2, 4-6, 12-14, and 20-22 hours after the treatment. The nominal air concentration immediately following the treatment was 17.7 µg/L. Average DDVP air concentrations were 0.63, 0.35, 0.21, and 0.12 µg/L at 1.5, 5, 13, and 21 hours after the application, respectively. It appears that the decline in DDVP concentration over time has a biphasic curve with a sharp drop up to 4-6 hours continued with a moderate decline from 4-6 hours up to 20-22 hours after the treatment when the last samples were taken. Assuming that the moderate decline will continue beyond 22 hours, a log linear regression analysis ($r^2 = 0.99$) of air concentrations at 5, 13, and 21 hours after the treatment predicts 0.1 and 0.06 µg/L DDVP at 24 and 32 hours after the treatment, respectively, according to the following equation:

  $y = (-0.7072) + (-0.0669)x$

  A reentry of 24 hours after the application allows for DDVP air concentrations to drop to a level that would result in an estimate of exposure that is shown below.

  $$C^a = \frac{(0.1\ \mu g/L \times 4\ hours) + (0.06\ \mu g/L \times 4\ hours)}{8\ hours} = 0.08\ \mu g/L$$

  $$ADD^b = \frac{0.08\ \mu g/L \times 840\ L/hour \times 6\ hours \times 50\%}{76\ kg} = 2.6\ \mu g/kg/day$$

  $MOE^c = 125$

a - Time-weighted average concentration 24-32 hours following treatment.
b - Based on inhalation rate of 0.84 m^3/hour and body weight of 76 kg (Thongsinthusak *et al*., 1993), inhalation uptake of 50% (Raabe, 1988), 6 hours of actual exposure during an 8-hour workday.
c - MOE for inhalation exposure based on an adjusted NOEL of 325 µg/kg/day for cholinergic signs and mortality observed in a rabbit inhalation study (Lim, 1998).

- Dermal exposure of workers using backpack sprayers was used as a worst-case scenario to estimate the exposure of applicators applying DDVP to livestock. The dermal exposure to workers using hand-held, or portable sprayers was several fold less than those using backpack sprayers. The estimate of exposure for livestock applicators in Table 1 was for workers wearing work clothing, rubber gloves, socks, and shoes. Coveralls would reduce dermal exposure to a level that, along with gloves and a half-face respirator requirement for inhalation exposure reduction, would result in the ADD after mitigation as shown in Table 3. All handlers should wear coveralls in addition to work clothing and chemical resistant gloves. Handlers applying DDVP to livestock and livestock and poultry premises should also wear a half-face respirator when handling inside enclosed structures.

Table 3. Estimates of ADD Before Mitigation and Estimates of ADD and MOE After Proposed Mitigation Measures

	ADD (µg/kg/day)				MOE[d]		ADD (µg/kg/day)
Work Task	Inhalation		Dermal		Inhalation	Dermal	Total
	Before[a]	After[b]	Before[a]	After[c]	After	After	After
Structural PCO	0.5	0.5[e]	8.7	0.9	650	625	1.4
Livestock applicator	55	2.4	7	0.7	135	714	3.1

a - Fong and Formoli, 1993

b – Based on inhalation exposure of 0.55 mg/m^3, exposure time of 8 hours for livestock applicators (Fong and Formoli, 1993), Inhalation uptake of 50% (Raabe, 1988), breathing rate of 0.84 m^3/hr, body weight of 76 kg, and half-face respirator providing 90% inhalation protection. (Thongsinthusak *et al*., 1993).

c – Based on dermal exposure of 3.8 mg/day for livestock applicators and 4.7 mg/day for PCOs, dermal absorption rate of 13% (Fong and Formoli, 1993), body weight of 76 kg, and coveralls providing 90% dermal protection (Thongsinthusak *et al*., 1993).

d - MOE for inhalation exposure based on an adjusted NOEL of 325 µg/kg/day for cholinergic signs and mortality observed in a rabbit inhalation study (Lim, 1998) and MOE for dermal exposure based on a NOEL of 500 µg/kg/day for RBC cholinesterase inhibition observed in a human acute oral study (Lim, 1998).

e – No mitigation.

General Populace Risk:

With the prohibition of the most residential and institutional uses, the potential for non-dietary exposure to the general population will be minor.

Expectations of Implemented Mitigation Proposal and Exposure Appraisal

The mitigation proposals are expected to reduce the estimated exposure for potential adverse health effects to the levels shown in Table 4. With the prohibition of the most residential and institutional, the potential for non-occupational exposure will be minor and therefore excluded from Table 4.

Table 4. DDVP Estimates of Exposure (µg/kg/day) and MOE Following Proposed Mitigation Measures

Exposure Category	ADD		Acute MOE		AADD[c]	Chronic MOE[d]	LADD[e]	Lifetime Oncogenic Risk[f]
	Inhalation	Dermal	Inhalation[a]	Dermal[b]				
Warehouse worker	2.6	na	125	na	0.12	208	0.07	1.4×10^{-5} to 2.5×10^{-5}
Structural PCO	0.5	0.8	650	625	0.11	227	0.06	1.2×10^{-5} to 2.1×10^{-5}
Livestock applicator	2.4	0.7	135	714	0.23	109	0.13	2.6×10^{-5} to 4.6×10^{-5}

a - MOE based on an adjusted NOEL of 325 µg/kg/day for cholinergic signs and mortality observed in a rabbit inhalation study (Lim, 1998).

b - MOE based on a NOEL of 500 µg/kg/day for RBC cholinesterase inhibition observed in a human acute oral study (Lim, 1998).

c - Based on 17, 30, and 27 days of exposure in a year (365 days) for warehouse worker, PCO, and livestock applicator, respectively (Fong and Formoli, 1993).

d - Chronic MOE based on a NOEL of 25 µg/kg/day (Lim, 1998).

e - Based on 40 years of work in a 70-year lifetime.

f - Oncogenic risk based on q1 of 0.0002 µg/kg/day and q1* of 0.00035 µg/kg/day for mononuclear leukemia in rat (Lim, 1998).

The above mitigation measures are expected to have the following effects on the 6 major categories of products currently registered in California:

1. Indoor and outdoor residential, institutional, and industrial uses
    a. *Deleting all indoor residential and institutional uses by voluntary label revision or by regulation.*

2. Stored commodity uses in warehouses.
    a. *Imposing a 24-hour reentry interval by voluntary label revision or by regulation.*
    b. *Requiring the proposed additional PPE for handlers by voluntary label revision or by regulation (the proposed additional PPE requirement is waived when using products with automatic application devices).*

3. Livestock, livestock premises, and poultry house uses.
    a. *Requiring the proposed additional PPE for handlers by voluntary label revision or by regulation.*

4. Pet collars
    a. *No expected mitigation.*

5. Pest strips for residential, institutional, industrial, agricultural commodity warehouse, and livestock premise uses.
    a. *See attachment I for details.*

6. Aerosol jet sprays for outdoor nuisance insect control.
    a. *Requiring the proposed additional PPE for handlers by voluntary label revision or by regulation.*

Bibliography

Fong, H.R. and Formoli, T.A. 1993. DDVP: Metabolic fate, dermal transport and human exposure data. Worker Health and Safety Branch, DPR, Sacramento, CA. HS-1540.

Knight, L.P. 1985. Lethalaire A-41 insecticide air concentration/worker exposure study. Virginia Chemical. DPR Registration Doc. No. 235-058.

Lim, L.O., Aldous, C.N., Gee, J.F., Fong, H.R., Formoli, T.A. and Rech C.J. 1996. DDVP risk characterization document. Medical Toxicology and Worker Health and Safety Branches, DPR, Sacramento, CA.

Lim, L.O. 1998. Addendum to dichlorvos (DDVP) risk characterization document. Medical Toxicology and Worker Health and Safety Branches, DPR, Sacramento, CA.

McDonald, E.C. 1991. Indoor fogger dermal and inhalation exposure study with DDVP. British Columbia Research corporation, British Columbia, Canada. DPR Registration Doc. No. 235-113.

Merricks, L.D. 1988. Exposure of workers to cyromazine during mixing, loading and application of Larvadex® 2 SL in poultry houses. DPR Registration Doc. No. 414-084.

Raabe, O.G. 1988. Inhalation uptake of xenobiotic vapors by people. California Air Resources Board, Contract A5-155-33. University of California, Davis, California.

Thongsinthusak, T., Ross, J.H. and Meinders, D. 1993. Guidance for the preparation of human pesticide exposure assessment documents. Worker Health and Safety Branch, DPR, Sacramento, CA. HS-1612.

ATTACHMENT I

Mitigation Proposal for DDVP Pest Strips

Department of Pesticide Regulation

Paul E. Helliker
Director

Gray Davis
Governor

Winston H. Hickox
Secretary, California
Environmental Protection Agency

M E M O R A N D U M

TO: Tobi L. Jones, Ph.D., Assistant Director
Division of Registration and Health Evaluation

FROM: Charles M. Andrews, Chief
Worker Health and Safety Branch
(916) 445-4260

DATE: September 11, 2000

SUBJECT: RECOMMENDED MITIGATION PROPOSAL FOR DDVP PEST STRIPS

On July 19, 2000, AMVAC presented their own version of the exposure/risk assessment to the Department of Pesticide Regulation's (DPR) management in response to the cancellation notice on DDVP pest strips. At that meeting, AMVAC also proposed some label amendments to address DPR's unacceptable margin of exposure (MOE) identified in the risk characterization document. Based on the concerns raised by Worker Health & Safety (WH&S) Branch scientists, DPR's Chief Counsel arranged a follow-up meeting with AMVAC on August 22, 2000, for the scientists to discuss and clarify the exposure assumptions and scenarios used in AMVAC's exposure/risk assessment.

After the August 22 meeting, WH&S Branch staff felt that a couple of scientific issues central to the calculation of acute inhalation exposure remained unresolved. AMVAC scientists assumed a lower initial air concentration (0.1 mg/m^3) for the use of a 21-gram strip in a normal size (150 cubic feet) closet. This lower estimate was assumed without empirical data and could not be accounted for after adjustment for strip size (i.e., mass or quantity). The data in the air monitoring study by Collins and DeVries (1973) indicated that the air concentrations at day 1 ranged from 0.03 to 0.12 mg/m^3 per 1,000 cubic feet per strip, with an average of 0.08 mg/m^3. In this study, fifteen homes were treated with DDVP pest strips (presumably 80 grams each). (Note: This study was made available to DPR scientists after the exposure assessment was completed. The highest value identified in this study (i.e., 0.12 mg/m^3) is similar to the air concentration (0.14 mg/m^3) used by WH&S Branch staff in their exposure assessment for DDVP pest strips).

Based on AMVAC's assumption of using 0.1 mg/m^3 air concentration resulting from the use of a 21-gram strip in a regular size closet, infants and elderly people can stay up to 19 hours in an adjacent bedroom. The MOE in this exposure scenario would be 100 (*see* Table 1, Attachment). Branch staff concluded that the initial DDVP air concentration for the same closet use scenario would be 0.2 mg/m^3 (based on assumptions specified in footnote *a* of Table 1), or twice that assumed by AMVAC scientists. In the absence of any supporting empirical data and primarily on the basis of pesticide quantity use, 0.2 mg/m^3 is an appropriate value to use under the use

scenario described above. This higher air concentration estimate suggests that during the first few days after treatment, an infant or a toddler could stay up to 10 hours in a bedroom where a regular size closet is treated with a 21-gram strip (*see* Table 1). The MOE in this exposure scenario would be 95 (*see* Table 1). If the exposure duration were 19 hours, the MOE would be 50 (*see* Table 1). WH&S Branch scientists recommend that no strips are used in closets of rooms occupied by infants, children, ill people, and elderly people. Infants or children may play, work on homework, and sleep in their rooms for periods longer than 10 hours. There is also a great possibility that the elderly and sick may read, rest, or sleep in their rooms for periods exceeding 10 hours.

In light of WH&S Branch staff's scientific concerns, it is proposed that the following labeling changes be adopted as practical mitigation measures for DDVP pest strips:

- As agreed upon previously, no 80-gram strips can be used in any *living* areas.
- DDVP strips can be used in attics and garages that are not used as living areas.
- DDVP strips of 5.25-grams can be used in kitchen cupboards.
- No more than one 21-gram strip can be used in one closet.
- No strips can be used in closets of rooms occupied by infants, children, ill people, and elderly people.
- Use-specific monitoring studies under practical maximum exposure conditions are needed to support any attenuation of any of the above restrictions.

References

Collins RD, DeVries DM, 1973. Air Concentrations and Food Residues from Use of Shell's No-Pest® Insecticide Strip. Bull Environ Contamn Toxicol. 9:227-233.

Attachment

cc: Sharon Dobbins, DPR's Chief Counsel
Gary T. Patterson, Ph.D., Chief, Medical Toxicology Branch
Barry Cortez, Chief, Pesticide Registration Branch
Michael Dong, Ph.D., WH&S Branch
Tareq Formoli, WH&S Branch

Attachment

Table 1. Margins of Exposure (MOE) for Use of DDVP Pest Strips Prior to and Following Mitigation

TWA Air on Day 1 in Closet (mg/m^3)[a]	Highest TWA Air Expected in Bedroom (mg/m^3)[b]	Inhalation Rate (m^3/hr)	Exposure Duration (hr)	Inhalation Exposure (mg/day)[c]	Absorbed Daily Dosage (µg/kg/day)[d]	Acute NOEL (µg/kg/day)	Acute MOE[e]
From the Department's Risk Characterization Document, Prior to Mitigation Based on the Use of 80-Gram Strips in Bedroom							
	0.140	0.252	24	0.85	40.32	325	8
***Following Mitigation with a 21-Gram Strip in Closet, Based on* AMVAC's Assumptions**							
0.1	0.014	0.252	8	0.03	1.37	325	237
0.1	0.014	0.252	10	0.04	1.71	325	190
0.1	0.014	0.252	12	0.04	2.06	325	158
0.1	0.014	0.252	19	0.07	3.26	325	100
0.1	0.014	0.252	24	0.09	4.11	325	79
***Following Mitigation with a 21-Gram Strip in Closet, Based on* WH&S Staff's Assumptions**							
0.2	0.029	0.252	8	0.06	2.74	325	118
0.2	0.029	0.252	10	0.07	3.43	325	95
0.2	0.029	0.252	12	0.09	4.11	325	79
0.2	0.029	0.252	19	0.14	6.51	325	50
0.2	0.029	0.252	24	0.17	8.23	325	39

[a] the basis for the use of 0.1 mg/m^3 by AMVAC is unclear (*see* text); the use of 0.2 mg/m^3 by Branch staff was based on the following: (0.1 mg/m^3 for each 1,000 ft^3) x (1,050 ft^3/150 ft^3) x (21 grams/75 grams), where the 75 grams were from averaging the 65- to 80-gram strips.

[b] the DDVP vapors from the closet are assumed to eventually perforate to the (closed door) bedroom with an air space ~ 7 times greater, resulting in a 7-fold dilution of air concentration at equilibrium; the air (concentration) in rooms with closets treated may not reach equilibrium due to the limited use of the 21-gram strips; however, this assumption cannot be subsantiated without some use-specific monitoring data.

[c] (inhalation exposure) = (TWA air level in bedroom) x (inhalation rate) x (exposure duration).

[d] (absorbed daily dosage) = (inhalation exposure) x (the 50% inhalation uptake default) x $(10.5 \text{ kg body weight for infants})^{-1}$.

[e] MOE = (no observed effect level [NOEL])/(absorbed daily dosage).

Paul E. Helliker
Director

Department of Pesticide Regulation

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M E M O R A N D U M

TO: Tobi L. Jones, Ph.D., Assistant Director
Division of Registration and Health Evaluation

FROM: Charles M. Andrews, Chief
Worker Health and Safety Branch
(916) 445-4222

DATE: September 25, 2000

SUBJECT: CLARIFICATION ON RECOMMENDED MITIGATION PROPOSAL FOR DDVP PEST STRIPS

The Pesticide Registration Branch raised a couple of questions concerning the labeling changes that were recommended in the above mitigation proposal from me to you dated September 11, 2000. This memorandum is to clarify those issues by way of revising slightly the labeling changes that were recommended in that proposal.

- No strips are to be used in any *living* areas except the following:
- DDVP strips can be used in attics and garages that are not used as living areas.
- DDVP strips of 5.25-grams can be used in kitchen cupboards.
- No more than one 21-gram strip can be used in one closet in each room.
- No strips can be used in closets of rooms occupied by infants, children, ill people, and elderly people.

Use-specific monitoring studies under practical maximum exposure conditions are needed to support any attenuation of any of the above restrictions.

cc: Sharon Dobbins, DPR's Chief Counsel
Gary T. Patterson, Ph.D., Chief, Medical Toxicology Branch
Barry Cortez, Chief, Pesticide Registration Branch
Michael H. Dong, Ph.D., WH&S Branch
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