Mary-Ann Warmerdam
Director

Department of Pesticide Regulation

Arnold Schwarzenegger
Governor

M E M O R A N D U M

TO: Joseph P. Frank **HSM-08003**
Senior Toxicologist
Worker Health and Safety Branch

FROM: Sheryl Beauvais *(original signed by S. Beauvais)*
Staff Toxicologist (Specialist)
(916) 445-4268

DATE: January 18, 2008

SUBJECT: REQUEST FOR WORKER HEALTH AND SAFETY STUDY ON RESIDUE TRANSFER FROM INSECTICIDAL CATTLE EAR TAGS

Recently, we have identified a data gap with respect to insecticidal ear tags used with cattle. Insufficient data are available for these products to allow us to estimate exposure. Exposure estimates are necessary to assure protection of those contacting active ingredient (AI) residues during legal uses of the product. Tags are made of plastic which has been impregnated with the AI. Product efficacy requires the AI to move to the tag surface, where it then volatilizes, is transferred to the animal's skin by contact, or undergoes some combination of both processes. Movement of residues to tag surfaces also makes them potentially available to transfer from tags to the hands of an applicator who removes tags from the package and places them into applicator pliers as demonstrated in Figure 1.

Figure 1. Instruction for Placement of Ear Tags in Applicator Pliers [a]

[a] Copied from KMG-Bernuth, Inc. (2006).

Labels for all products registered in California specify the use of special pliers to insert tags into cattle ears. Most labels also specify that gloves should be worn. With respect to gloves, labels contain statements that are similar to the following:

- "Wear protective gloves."
- "Wear clean gloves daily when applying tags."
- "Wear rubber or non-permeable protective gloves when applying tags."

Wearing gloves would mitigate a portion of the exposure an applicator might receive. The standard default protection factor used in exposure assessments for handlers wearing gloves is 90% (Aprea *et al.*, 1994). The protection factor for certain gloves might be greater or less than 90% for various AIs released from cattle ear tags and various gloves. Ear tag products registered in California have several different AIs, as shown in Table 1. Numerous studies have investigated the penetration of various AIs from liquid formulations through glove materials. For example, two studies of glove permeation by endosulfan were both conducted using the emulsifiable concentrate (EC) formulation (Ehntholt *et al*., 1990; Khan *et al.*, 1997). In both studies, multiple glove materials were tested. Endosulfan rapidly penetrated through nitrile, but Viton and Silver Shield gloves were effective barriers to endosulfan. However, the range of protection factors reported in Ehntholt *et al*. (1990) and Khan *et al*. (1997) suggest that various gloves would not be anticipated to protect skin equally. If a handler selects a material that an AI penetrates more readily, the protection factor could be less than 90%. Furthermore, permeation through glove material is not the only route by which hands can be contaminated inside gloves, as pesticides can enter the gloves around the cuffs or hands can be contaminated when gloves are removed and put back on (Garrod *et al*., 2001; Rawson *et al.*, 2005). Thus, exposure to residues is potentially a health concern even if gloves are worn.

Table 1. Cattle Ear Tags Registered in California

Product Name [a]	EPA Reg. No.	Active Ingredient(s) and Concentration(s)
Pyrethroids		
Cyclence Ultra Insecticide	11556-131-ZA	β-Cyfluthrin 8%, PBO [b] 20%
Saber Extra Insecticide	773-75-AA	λ-Cyhalothrin, PBO 13%
Python Insecticide	39039-4-AA	(S)-Cypermethrin 10%, PBO 20%
Python Magnum Insecticide	39039-11-AA	(S)-Cypermethrin 10%, PBO 20%
Gardstar Plus Insecticide	39039-1-AA	Permethrin 10%
Atroban Extra Insecticidal	773-78-ZA	Permethrin 10%, PBO 13%
Organophosphates		
New Z Diazinon Insecticide	270-260-AA	Diazinon 18%, PBO 2%
Stocker Insecticide	4691-142-AA	Diazinon 20%
Optimizer Insecticide	39039-3-AA	Diazinon 21.4%
Warrior Insecticide	39039-6-AA	Diazinon 30%, Chlorpyrifos 10%
Patriot Defense System Insecticide	4691-148-ZA	Diazinon 40%
Patriot Defense System Insecticide	61483-80-AA	Diazinon 40%
Organochlorines		
Avenger Insecticide		Endosulfan 30%

[a] All products have the words "ear tag" or "cattle ear tag" in their names, omitted here.
[b] PBO: piperonyl butoxide.

Preliminary Exposure Estimates for a Product

Potential scenarios of concern are short-term exposure, in which an applicator handles a large number of tags in a day, and seasonal exposure, in which several tags are handled daily on multiple days. The number of tags that could be handled in a day (400), which was initially based on a default from U.S. EPA (Dawson, 1999), has since been confirmed to be a reasonable high-end number by experts in California. More information is needed for seasonal exposure; however, based on limited information an applicator might be assumed to handle 20-40 tags per day.

For a preliminary short-term exposure estimate in the absence of chemical-specific data, the dermal contribution to exposure is calculated with the following assumptions:

- For absorbed-dose estimates, each individual is assumed to weigh 70 kg (Thongsinthusak *et al.*, 1993).
- Dermal absorption of the AI is assumed to be 50%, the default used by DPR in the absence of acceptable chemical-specific data (Donahue, 1996a). In the example below, dermal absorption of the AI permethrin is assumed to be 28%, based on data submitted to DPR (Thonginsthusak and Ross, 1995)
- Applicator exposure is assumed to equal a default of 1% of the AI contained in each ear tag (U.S. EPA, 1997).
- A protection factor of 90% is assumed for use of chemical-resistant gloves (Aprea *et al.*, 1994).

An example product is Atroban Extra Insecticide Ear Tags (EPA Reg. No. 773-78-AA). Tags are sold in packages of 20. As stated on the product label, individual tags each weigh 9.5 g and contain 10% permethrin by weight. As can be seen in Table 1, all ear tags contain at least 10% AI. Each ear tag weighs at least 9.5 g (some tags, including Avenger, Cyclence, Optimizer, and Warrier Insecticide Cattle Ear Tags, weigh 15 g each).

Short-term (acute) exposure is calculated as follows:

- 0.95 g permethrin is in each tag (10% of 9.5 g)
- Exposure per tag = (0.01) x (0.95 g) = 0.0095 g or 9.5 mg.
- Individual exposure per day = (400 tags) x (9.5 mg/tag) x (0.1) = 380 mg/day
- Absorbed dose = [(380 mg/day) x (0.28)]/(70 kg) = **1.52 mg/kg/day**

This estimated dose exceeds the default of 0.0003 mg/kg/day, established by Donahue (1996b) for insignificant exposure, raising the possibility that there might be a potential health concern for some of the ear tag products.

Request for Dislodgeable Surface Residues

The default of 1% of total dose transferred during handling of an ear tag is based on an assumption made by U.S. EPA exposure assessors when estimating exposure for handlers of insecticide-impregnated pet collars (U.S. EPA, 1997). No better assumption is presently available for this scenario. An estimate of residues that can be dislodged while a tag is handled would allow the exposure estimate to be refined. One approach would involve wiping a series of tags with a swatch of glove material or cotton gauze. A standardized wiping technique should be used on each tag, and would result in an estimate of dislodgeable surface residues (DSR). A study design is proposed below; the design may need to be modified to achieve a feasible study.

- **Test materials** could be selected from commercially available ear tags (available products should include most of the tags listed in Table 1).
    - At least three (3) different products should be selected. Products should include at least one pyrethroid and at least one organophosphate (Avenger was recently registered, and might not be commercially available).
    - Like dislodgeable foliar residues, DSR are likely to be chemical-specific, and might also vary with AI concentration in the tag and the plastic tag matrix. Because of this, an ideal study would analyze all available tag products. Due to resource limitations, it may not be feasible to include all products. As the purpose of this study is to assess whether the amount transferred is substantially below the 1% that was assumed in the preliminary exposure estimate, it is desirable to include a range of tags.
- **Sample size:** For this proposed study design, a sample is defined as a group of tags that will be wiped with a single swatch. The swatch will then be analyzed for transferred residues.
    - The number of tags in each sample will need to be determined from a preliminary test, to assure that detectable levels of residues can be recovered from samples. A sample could consist of all tags in a package of 20, for example.
    - Once the number of tags needed for each sample is determined, then at least three (3) replicate samples of each product should be studied to allow determination of the variability of the DSR between samples. For a balanced study design, each replicate should be done by a different person; that is, three people should do the wipes, and each person should handle all products.

For the standardized wiping method, both sides of each tag should be simultaneously wiped with the dry swatch, with a consistent pressure applied with each wipe. Each tag should be picked up and held as shown in Figure 1, wiped, then set aside. As handlers are anticipated to wear gloves, the DSR would not require a dislodging solution.

Presently, it seems unlikely that exposure assessors would need to estimate exposures for fewer than 20 tags per day, and unless the DSR from groups of 20 tags are well above laboratory detection limits, there seems little value in attempting to measure DSR for a single tag or groups of a few tags.

The study design proposed above mentions a minimum number of 3 products to be included, as well as a minimum number of 3 replicates. If resources are severely limited, then it would be acceptable to have only two replicates instead of three (must have at least two), and two products instead of three. Conversely, if additional resources are available to expand on the proposed design, it would be better to increase the number of products analyzed than to increase the number of replicates beyond three.

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cc: Susan Edmiston, Chief, WHS Branch
George Farnsworth, Environmental Program Manager I, WHS Branch
Janet Spencer, Research Scientist II, WHS Branch