



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

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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

james@elversonpuzzle.com

Dear Mr. TerBush:

Thank you for your email of May 4, 2011, asking additional questions about our review of MRID 48129614. I am pleased to have an opportunity to respond to your concerns.

Comment 1:

It also must be pointed out that the current labeled application rate (4.0 mL) for Sergeant's etofenprox spot-on for dogs (EPA Reg. No. 2517-13) is TWICE the application rate that was originally proposed and used in the above companion animal safety study, and it is considerably larger than the application rate of similar registered products.

Response 1:

The maximum application rate, expressed in terms of mg/kg of dog body weight, occurs when 2.0 ml of the subject product is applied to a 1.81 kg (4 lb) dog. The dose to a 1.81 kg dog is 629 mg of etofenprox/kg of dog body weight, which is less than the dose applied in the Companion Animal Safety study. Dr. Backus concluded that the 629 mg/kg rate was safe when applied to dogs. Any rate below that is also safe.

The 4 ml dose, when applied to 11-20 lbs dogs, results in a maximum dose of 456.31 mg etofenprox/kg of dog body weight (11 lb dog = 4.99 kg body weight).

Comment 2:

No mention of any risk from potential human exposure.

As you know, EPA human health risk assessments of pet spot-on products are based on the assumption that there is an even loading of pesticide residue across the entire surface of the pet, and risks are always assessed on Day 0 (the day of the application) because it is assumed that people – including children – will have contact with their pet immediately following application.

Why does the EPA assume that an even loading of pesticide residue across the entire surface of the pet occurs immediately following application of a spot-on product, especially when the facts indicate otherwise?

How can that assumption be viewed as conservative when it has the potential to greatly underestimate exposure to treated pets?

Response 2:

The EPA is dedicated to the protection of human health risks associated from exposures to pesticides, particularly those used in residential environments. The EPA assesses all pet pesticide treatments, including spot-on products, using a screening level approach with conservative assumptions and refines these as appropriate given data availability and applicable changes in methodologies. This process is referred to as a tiered risk assessment method. The use of such an approach is consistent with overall agency guidance for exposure and risk assessment. The methods used to evaluate these types of exposures are outlined in the *Standard Operating Procedures (SOPs) for Residential Exposure Assessments* (i.e., "SOPs" or "Residential SOPs"). They evaluate extensive dermal contact from young children and adults hugging treated animals and toddlers mouthing their hands after contact with their treated animals (e.g., vigorous petting).

The EPA assumes that, upon treatment, the active ingredient is loaded across the entire surface area of a treated pet. This assumption was employed upon development of the Residential SOPs to account for the potential of adult and child contact with the entire surface area of the treated animal (for all pet product formulations assessed) because it is unlikely that contact is confined to a particular area. This methodology is coupled with conservative, screening level assumptions of contact and transfer. For example, the EPA assumes a 20 percent transfer of the active ingredient from the surface area of the animal to the surface area of the exposed individual (i.e., hug, hands). In effect, 20 percent of a pet product application is assumed to be available for human dermal contact or ingestion. Based upon a recent review of all available residue transfer exposed studies, the 20 percent default assumption was determined to be highly conservative, approximately 20 times greater than that determined from the review.

The EPA refines its methodologies as more information becomes available to ensure that its assessments reflect the current state of the science. The EPA is currently in the process of updating the residential standard operating procedures for conducting exposure assessments to pet products using the most recently available data and in a manner that is consistent with the use of data involving human research. On October 6-9, 2009, a revised version of the Residential SOPs was reviewed by the Federal Insecticide, Fungicide and Rodenticide Act Scientific Advisory Panel. Meeting minutes from the FIFRA SAP were received on December 16, 2009. The EPA is in the process of reviewing and incorporating these comments; however, no specific date has been identified for the completion and subsequent use of the revised Residential SOP document.

I hope you find these responses helpful in understanding the EPA's human health risk assessment process.

Sincerely,



Claire M. Gesalman, Chief
Communication Services Branch