



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

MAY 2 2011

Dear Mr. TerBush:

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Thank you for your emails of April 8 and April 13, 2011, to Dr. Byron Backus of our Registration Division requesting information about the technical review of MRID 481296-14—specifically, the comment:

The review of February 24, 2010 included the comment [p. 15] that application sites had an oily or wet appearance and that persistence of test substance on the hair of dogs for more than 14 days is of concern due to potential human exposure.

Your correspondence was forwarded to me since my office is responsible for responding to inquiries from the public. You wish to know why the Technical Review Branch concluded that the registrant's response was adequate, in view of the fact that the product has been assigned to Toxicity Category II for eye exposure and requires child-resistant packaging because of its toxicity.

As you know, companion animal safety studies are intended to demonstrate that pesticide formulations for the treatment of external pests on domestic animals have an adequate margin of safety if the products are misused (overused). For that reason, they include exaggerated application rates. In the case of the study identified by MRID 481296-14, the amount applied to the test dogs was five times the amount that the Agency allows and that a pet owner would apply. The results from companion animal safety studies are not used to determine potential human exposure.

EPA assesses the post-application exposure of humans from treated pets in accordance with the "HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments (December 19, 1997)." The daily dose used to assess exposure is based on the amount of active ingredient handled on the day of treatment, assuming the maximum label rate and a 20 percent rate of transfer from the pet to humans (adults/toddlers). These assumptions are conservative and result in assessments that are not likely to underestimate exposure from treated pets.

I hope this information answers your questions. Please send any further inquiries to me in the Communications Services Branch, Field and External Affairs Division, Office of Pesticide Programs, at [gesalman.claire@epa.gov](mailto:gesalman.claire@epa.gov) or at U.S. EPA, 1200 Pennsylvania Avenue, NW, Mail Stop 7506P, Washington, DC 20460. Our scientists and the staff in our regulatory divisions frequently do not have the time to respond directly to the emails and letters they receive, so our procedure calls for most inquiries to be answered by my office.

Sincerely,

A handwritten signature in black ink that reads "Claire Gesalman".

Claire M. Gesalman, Chief  
Communication Services Branch