

US EPA ARCHIVE DOCUMENT



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

MAR 25 1997

MEMORANDUM

Subject: FIPRONIL (FRONTLINE) For Fleas on Cats and Dogs.
Review of Protocols to Determine Worker Exposure.
(No MRID #s)[Chem ID# 129121][DP Barcodes D229728 and D229718]
[Case #s 014261 and 046906]

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Occupational and Residential Exposure Branch

To: Michael S. Metzger, Chief
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Thru: Ed Zager, Chief
Occupational and Residential Exposure Branch

Introduction

Rhone Merieux, Inc., has submitted two protocols. One protocol is to determine potential dermal exposure to commercial pet groomers from the use of Frontline Top Spot on dogs (MRID # 229728). The other protocol is to determine potential dermal and inhalation exposure to commercial pet groomers from the use of Frontline Spray Treatment on dogs (MRID # 229718). In FAX dated March 5, 1997 from J. Bond, Rhone Merieux, to E. Zager, EPA, Rhone Merieux proposed an amendment to both protocols to bring them in line with the proposed Series 875 Exposure Guidelines. The dermal and inhalation portion of these studies (Phase I) will be conducted by ABC Laboratories California and the analytical portion will be conducted by Rhone Merieux.

RECOMMENDATIONS

OREB recommends that the petitioner proceed to conduct the inhalation and dermal exposure studies for commercial pet groomers from the use of fipronil on dogs, provided he can follow our suggestions in the conclusions below. Since the petitioner proposes to conduct these studies in California OREB recommends that the appropriate California officials be contacted for approval before starting the studies.

Conclusions

1. OREB concludes that potential dermal exposure determined from use on dogs only is acceptable in that workers potentially can get more exposure from handling 30 lb dogs than cats.
2. OREB suggests that the petitioner be encouraged to use different breeds of dogs with varying lengths of hair and curl in this study. This information should be in the final report for us to assess the differences in human exposure.
3. OREB suggests that the petitioner present evidence to show that the treatment area; i.e. the table top, floor, etc., being wiped down between each treatment is standard grooming procedure across the country, or conduct an additional dermal exposure study in another part of the USA.

4. OREB suggests that the petitioner contact the appropriate California authorities concerning conduct of studies with human volunteers where the use of PPE is not followed; ie, use of latex gloves to rub down the dogs fur. Second, we suggest that the petitioner consider washing the gloves to get the potential exposure instead of using bare hands then washing the hands to determine the amount of exposure.
5. OREB prefer the sectioning of the garment used in the passive dosimetry be done as proposed originally, unless there is a question of sensitivity. If ranging studies indicate there can only be positive results from the revised sectioning, then the revised sectioning scheme will be acceptable.
6. OREB suggest that the petitioner show in his final report that the hand wash solution is the most appropriate one when reviewed against the product chemistry solubility data.
7. OREB suggests that the petitioner present a rationale for using Nalgene containers to store the hand wash solutions over other types of containers, eg, glass. Our concern is the adherence of fipronil to the surface of the container.
8. For field fortifications the petitioner proposed using triplicate low, medium, and high levels; yet no numerical values were proposed. OREB suggests that the petitioner conduct initial ranging tests before the actual studies to accurately determine the values to use in the low, medium, and high fortifications. OREB expects that the validation data bracket the exposure test results. This guidance also applies to the travel spikes.
9. Since the analytical method section of the protocol is sparse OREB suggests that the petitioner review the environmental chemistry methods requirements published in 1995 as well as the residue chemistry analytical methods requirements found in the 860.1340 guidelines before starting to generate method validation data.

DETAILED CONSIDERATIONS

Frontline Top Spot (EPA Reg. No. 65331-3)[9.7% a.i. fipronil]
Rhone Merieux Study Number SAFXT047, ABC/CA study No. 96613

Frontline Top Spot is currently conditionally registered to control fleas and ticks on cats and dogs. In this study the petitioner is proposing that potential dermal exposure be determined from use on dogs only. OREB has no objection. We concur that workers potentially can get more exposure from handling 30 lb dogs than cats.

The petitioner proposes using 16 workers (replicates), 8 workers in each of two facilities in the central San Joaquin Valley in California to determine dermal exposure. Worker exposure will be determined by passive dosimetry.

A monitoring period will consist of an eight hour day with a worker handling 8 dogs. OREB's concern is not so much that grooming varies around the USA, but that grooming varies among the different breeds of dogs. The petitioner is encouraged to use different breeds of dogs with varying length of hair and curl. This information should be in the final report so that we can assess the differences in human exposure. Workers will use the typical end-use pour-on product containing 0.76 ml for dogs less than 22 lbs and the 1.34 ml product for dogs up to 44 lbs. The product will be applied as a single spot directly to the dogs skin without excess contact with the fur. The dogs will be treated consecutively with the treatment area; ie, the table top floor, etc., wiped down between each treatment. OREB suggests that the petitioner present evidence that this will be standard grooming procedure across the country, and that there is little variation in use conditions in a typical grooming shop.

Workers will wear the standard PPE equipment that is listed on the label, ie, latex gloves, for use on four dogs, then treat 4 dogs without wearing gloves. OREB has two concerns. We suggest that the petitioner contact the appropriate California authorities concerning conduct of studies with human volunteers where the use of PPE is not followed. Second, we suggest that the petitioner consider washing the gloves to get the potential exposure instead of using bare hands then washing the hands to determine the amount of exposure.

The petitioner proposes using short sleeve shirts and short pants over a prewashed one piece cotton white long underwear as the dosimeter. Initially, the petitioner proposed at the end of the monitoring period the white underwear would be sectioned into lower body thighs and shins, upper body back and chest, arms shoulder, upper, and lower. In the March 5 amendment the petitioner suggested the white underwear be sectioned into bottom half (waist down), back, upper arm, and lower arm. OREB prefers the sectioning as proposed originally, unless there is a question of sensitivity. If ranging studies indicate there can only be positive results from the revised sectioning, then the revised sectioning scheme will be acceptable.

The petitioner proposes that the hand washing be two times 300 mls 10% aqueous isopropyl alcohol for 45 seconds. OREB suggest that the petitioner show in his final report that the hand wash solution is the most appropriate one when reviewed against the product chemistry solubility data. The petitioner proposes pouring duplicate 100 mls aliquots into Nalgene jars. OREB suggests that the petitioner present a rationale for using Nalgene containers to store the hand wash solution over other types of containers, eg, glass. Our concern is the adherence of fipronil to the surface of the container.

For field fortifications the petitioner proposed using triplicate low, medium, and high levels; yet no numerical values were proposed. OREB suggests that the petitioner conduct initial ranging tests to determine what will be the spiking levels for low, medium, and high fortifications before doing the actual studies. OREB expects that the validation data bracket the exposure test results. This guidance also applies to the travel spikes.

OREB notes that the analytical method section of the protocol is sparse. We suggest that the petitioner review the environmental chemistry methods requirements published in 1995 as well as the residue chemistry analytical methods requirements found in the 860.1340 guidelines before starting to generate method validation data. The analytical method used to generate the residue levels reported needs to be properly validated before OREB can accept the dermal exposure test results.

Frontline Spray Treatment (EPA Reg. No. 65331-1)[0.29% a.i. fipronil]
Rhone Merieux Study Number SAFXT046, ABC/CA study No. 96612

This protocol is nearly identical to that reviewed above. The only difference is the use of the spray at a rate of 2 pumps per pound of dog. Thus, the petitioner is including inhalation exposure in this protocol. OREB has no suggests on the inhalation exposure part of the study. Comments on other portions of this protocol are the same as for the protocol above and are incorporated herein by reference.

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