

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

May 27, 2003

MEMORANDUM

Product Name: FRONTLINE TOP SPOT FOR CATS
EPA Reg. No.: 65331-2
DP Barcode: D288436
Case No: 046906
Submission: S620232
Chemical: 129121 Fipronil

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505C)

To: Ann Sibold, PM 03
Insecticide Branch
Registration Division (7505C)

Company: MERIAL LIMITED

ACTION REQUESTED: "Please review the attached incident annual analysis (no guideline, no MRID) and determine if: 1. label changes are needed, and 2. the requirement for annual analysis of incidents should continue..."

BACKGROUND: According to the report received from the registrant, this product was involved in 93 incident reports involving a total of 111 cats (and kittens). There were 12 feline fatalities.

COMMENTS AND RECOMMENDATIONS:

1. This document is labeled as containing Confidential Business Information (CBI). The attachment containing CBI includes a page giving the number of doses sold for the different products, as well as summaries of adverse reactions in different species and details of incidents in which deaths occurred. While the number of doses sold for different products is CBI, the remainder of the information is 6(a)(2) data which the registrant has a responsibility of reporting to the Agency, and this cannot be classified as CBI.
2. Any 6(a)(2) data should be labeled as such and sent by the registrant to the Document Processing Desk (7504C); the ultimate referral would be to the 6(a)(2) Analysis and Coordination Team.
3. Of the twelve feline fatalities associated with exposure to this product, one cat was diagnosed with meningitis, while another was diagnosed with Eosinophilic Poliomeningoencephalitis due to parasite migration. In another incident, 3 cats died after one room in the basement was sprayed with permethrin. Although the owner had closed the door to this room, cats are known to be very sensitive to this active. In a second incident, two cats died but a dog in the same household had been treated with a permethrin spot-on. In yet another incident, the cat that died had also been treated with another product (Adams flea and tick spray).
4. There were also 5 adverse incidents involving "non-target" species (three rabbits, one guinea pig, and one Shih Tzu dog), although only one death (a rabbit) occurred. The product label includes the statements: "Use on cats only. Do not use of rabbits. Do not use on other animals."
5. There appears to be nothing in the data that would indicate any one particular breed of cat is more susceptible than another. Domestic shorthairs represented 51.4% of the incident reports, but this probably reflects a predominance of domestic shorthairs in the overall pet cat population.
6. Label revisions do not appear to be in order.