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

JAN 22 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID. No. 010308-00011. 90 Day Dermal Studies for Sumilarv.

Tox. Chem. No.: 129032
DP Barcode #: D220238
D220532
Record No. : S494440
S495384

FROM: Melba S. Morrow, D.V.M. MSM 11/27/95
Review Section II, Toxicology Branch I
Health Effects Division (H7509C)

TO: Joe Tavano/ Rick Keigwin PM 10
Registration Division (H7505C)

THRU: Joycelyn E. Stewart, Ph.D. 11/29/95 KB 12/15/95
Head, Section II
Toxicology Branch I
Health Effects Division (H7509C)

Action Requested: Waiver of 90 day dermal study for Sumilarv (Nylar, Pyriproxifen).

CONCLUSIONS:

The request for waiver of the 90 day dermal toxicity study for Sumilarv (pyriproxifen) can be granted based on the representative labels for end-use products containing Sumilarv (pyriproxifen). None of the labels for these products indicate that the pyroproxifen concentration is more than 5% and this level of exposure is not likely to be toxic, given the lack of dermal toxicity associated with repeated use of the technical.

The results of the 21-day dermal toxicity study demonstrate that the Sumilarv component of end use products would not be expected to cause systemic or dermal effects at doses up to 1000 mg/kg. The 21 day dermal toxicity study had not been reviewed at the time of our suggestion that a 90 day dermal study may be required.

It is noted that the acute data bases for the three end-use products for which labelling was provided to HED do not appear in our files for Sumilarv or Nylar. Information on the toxicity categories for these products are not a part of our toxicology profile for Sumilarv. Please forward copies of reviews so that this information can be included in the toxicology records for the parent compound.

Information contained on the end-use labels for combination products containing Sumilarv should be accurate and as consistent as possible. The information pertaining to the application of the compound and any precautionary measures should be clearly stated.

Background Information and Discussion:

Labels for several end-use products containing Sumilarv were submitted to Toxicology Branch I and a question was been posed on HED's requirement for a 90 day study for these end use pet products. Labels for other pet products were provided as an example of products which did not require a 90 day dermal toxicity study. While 90 day dermal studies have not routinely been required by HED on end-use pet products, HED recognizes that there is a population of individuals that would be exposed continuously and deliberately to active ingredients in final formulation products by virtue of their occupations (groomers, veterinary personnel).

Labelling should address any concerns for potential hazards associated with the use of these end-use products. However, information contained on these end-use product labels provided to HED by Registration Division is inconsistent, inadequate and in some instances, contradictory.

In the case of the Adams product (Adams Flea and Tick Mist with Nylar), the information contained in the "Human" subheading of the "Warning Section" contains a statement that the product is harmful if swallowed or absorbed though skin. The section goes on instruct the user to avoid contact with skin. Under "Practical Treatment", there is the advice to wash with plenty of soap and water and to seek medical attention. Contrary to the information contained in these sections on the labelling, the "Directions for Use" instruct the user to use their fingertips to rub into the face, around the mouth, nose and eyes of the animal being treated.

In this case a recommendation to wear gloves is appropriate and would satisfy concerns regarding the safe use of the product when repeated purposeful exposure is expected.

A similar concern does not exist for the Farnam label (Purge Plus Insecticide) because the directions for use do not advocate user contact with the active ingredients.

For the Ptenocide product (Ptenocide Pet Spray), it is noted that three of the six active ingredients are the same as those found in the Adams product. Were the acute toxicity profiles of the Adams product and Ptenocide such that the the label precautionary statements would differ with respect to warnings?