

US EPA ARCHIVE DOCUMENT



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

APR 19 1993

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Id#: 000270-ELG and 000270-ELN. FARNAM CRASH!
WIPE ON INSECTICIDE/REPELLENT and FARNAM CRASH!
FLY SPRAY CONCENTRATE. Review of a domestic
animal safety study with horses.

TOX CHEM No.: 271DD, 670, 715¹
PC No.: 109702, 067501, 069001
Barcode No.: D188760 and D188762
Submission No.: S436293 and S436299

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TO: George LaRocca/John Hebert
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THROUGH: Marion Copley, DVM, Section Head *Marion Copley 4/16/93*
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I. CONCLUSION

The domestic animal safety study conducted with FARNAM CRASH! Fly Spray Concentrate (EPA Reg. No.: 270-ELN) was determined to be ACCEPTABLE and to demonstrate no reactions when applied at 2X the label usage rate on a daily basis for 10 days.

The product FARNAM CRASH! Wipe on Insecticide/Repellent (Reg No.: 270-ELG) is considered sufficiently similar to the tested product such that the study can also be used to support the registration of this product.

¹Active ingredients are cypermethrin, pyrethrins and piperonyl butoxide.
See next page for composition of actives in each formulation.



II. ACTION REQUESTED

The Farnam Companies (refer to letter from Leland Veith, DVM, dated February 4, 1993) has submitted a domestic animal safety study (MRID No.: 426579-00) in support of their two products FARNAM CRASH! WIPE ON INSECTICIDE/REPELLENT (EPA Reg. No.: 270-ELG) and FARNAM CRASH! FLY SPRAY CONCENTRATE (EPA Reg. No.: 270-ELN) for use on horses. This study is a second attempt to demonstrate the safety to horses for these products. The first study (refer to HED Document No.: 008297, dated March 20, 1991) clearly indicated that application of the product at what was designed to be 4X the label application rate resulted in dermal irritation to the horses. This application rate, however, was more likely 17X the label dosage level because of multiple applications and the horses were not washed between applications. As per discussion with the company (refer to HED Document No.: 008297) a modified protocol for a new study was agreed upon. The new study has been reviewed and the following comments apply.

III. Toxicology Branch Comments

1. The study demonstrated that application at 2X the label rate (for FARNAM CRASH! Fly Spray Concentrate, Reg. No.: 270-ELN) on a daily basis for 10 days did not result in dermal irritation or other signs of reactions. Toxicology Branch considers this an adequate demonstration of this product for use on horses even though the "3 to 5X factor" was not demonstrated. The product was applied in this study on a daily basis and the label specifies that the product should not be used more than once every 5 to 7 days.
2. The product FARNAM CRASH! WIPE ON Insecticide Repellent (Reg. No.: 270-ELG) was not tested on horses in this study. This product, however, is considered essentially similar to the tested product such that the domestic animal safety study conducted can be used to support both products. For example, the product FLY SPRAY CONCENTRATE (EPA Reg. No.: 270-ELN) contains 0.6% cypermethrin, 0.8% pyrethrins and 6.4% piperonyl butoxide. The product WIPE-ON INSECTICIDE/REPELLENT contains 0.15% cypermethrin, 0.2% pyrethrins and 1.63% piperonyl butoxide.
3. Toxicology Branch defers to Registration Division for the label review for the signal word and precautionary statements for both of these products.

(86-1. FARNAM CRASH! - 73)

Reviewed by: John Doherty, Ph.D. (H7509C)
Section IV, Toxicology Branch I
Secondary reviewer: Marion Copley, DVM (H7509C)
Section IV, Toxicology Branch I

John Doherty 4/16/93

Marion Copley 4/19/93

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DATA EVALUATION REPORT

STUDY TYPE: 86-1. Domestic Animal Safety Study - Horses.

MRID NO.: 436579-01

TOX. CHEM. NO.: 271DD, 670, 715¹
PC No.: 109702, 067501, 069001

TEST MATERIAL: Farnam Crash! Concentrate (Lot #SPI-6128, Sample Id No.: TAA 00992).

STUDY NUMBER(S): BLAL No.: 132-001-22.

SPONSOR: Farnam Companies, Inc.

TESTING FACILITY: Bio-Life Associates, Ltd. Neillsville, Wisconsin

TITLE OF REPORT: "Farnam Crash Concentrate 270-ELN: Confirmation of the Safety of an Emulsifiable Concentrate Repellant for Horses"

AUTHOR(S): D.W. Fletcher and J.A. Mumper

REPORT ISSUED: January 29, 1993

STUDY DATES: October to November, 1992

CONCLUSIONS:

Repeated application (10 daily doses) of 2X the recommended usage rate for FARNAM CRASH! Fly Spray Concentrate does not result in dermal irritation or other reactions in horses.

Test Species: Mixed bred horses. Dose Levels: 2X label dose level applied on daily basis (label rate is once every 5-7 days).

Classification: ACCEPTABLE

Quality Assurance Statement: Provided
Good Laboratory Practice Statement: Provided

REVIEW

Experimental Constants:

¹The three active ingredients are cypermethrin (.6%), pyrethrins (.8%) and piperonyl butoxide (6.4%).

5

Test System: Four "low-level pigmented" horses (2 geldings and 2 mares) that were between 5 and 7 years old were used for this study. They were obtained from a local ranch. Their general health was assessed by a veterinarian. They were maintained for 31 days in "quarantine". These horses were described as having a "short summer coat". The manes were either clipped short prior to purchase or clipped after being received.

Basic Experimental Design:

The horses were "divided" down the middle from nose to tail and the right side (as viewed from the rear) was selected to receive the test chemical treatment. The left side was not treated and served as the control. Treatment consisted of first diluting the test material as received 1:1 with water (tap water). Application to the horses body was made by spraying with a plastic trigger sprayer. Application to the face was made by first applying the test material to a turkish towel and then wiping the face. The application was reportedly done so as not to soak the hair or skin of the horse and to prevent run-off. Six to eight hours after application, each horse was said to be wet down with tepid water and washed with a "hypoallergenic" shampoo (DVM Hylt*efa Brand Shampoo), rinsed and then dried with turkish towels. The procedure of application of the test material followed by washing was repeated each day for a period of 10 days. The average daily application ranged from 48 to 53 grams. The daily applications ranged from typically 30 to 60 gms per horse. During the experiment, the horses were kept in a dairy barn with ten hours of fluorescent light per day. The temperature during the test period was 59°C with relative humidity of 69%.

The effect of the test product was reportedly assessed by a licensed veterinarian at 15, 30 and 60 minutes post application. Daily observations for signs of erythema-eschar, edema or irritability were made.

RESULTS:

No signs of irritation or reactions to treatment were reported. All scores for erythema-eschar and edema were zero.

CONCLUSION: This study is ACCEPTABLE. The study demonstrates that repeated application (10 daily doses) of 2X the recommended usage rate for FARNAM CRASH! Fly Spray Concentrate does not result in dermal irritation or other reactions in horses.

Note: Although the study uses only 2X the label recommended dosage rate, the product was applied on a daily basis whereas the label usage rate calls for applications on not more than 5-7 days. Thus, TB-I considers that this study demonstrates the safety of this product for use on horses.