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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

EFFICACY REVIEW

Date in: 9/22/95 Date out: 12/5/95

Registration Number: 011556-RRI

Date Division Received: 9/26/95

Type of Product: 10% Solution

MRID No. 437941-01; 437941-02

Study titles - "Efficacy Evaluation of Bay t7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Adult Fleas and Flea Eggs on Cats" and "Controlled Field Trials on the Efficacy and Tolerance of a Spot-On Formulation of Imidacloprid (BAY NTN 33893) for Control of the Cat Flea (C.Felis) in Domestic Cats"

Product Manager: Dennis H. Edwards, Jr.

Team Reviewer: Portia Jenkins

Efficacy Reviewer: Paul Schroeder

Product Name: imidacloprid, Code numbers: NTN33893 and BAYt7391

Company Name: Miles Laboratory, Bayer Corporation

Submission Purpose: Support registration of Advantage 9 & 18 Insecticide products to control fleas on cats.

Chemical and Formulation: 10% imidacloprid W/V 10 mg/kg body weight placed on back of neck.

Claims Wanted: Control of cat fleas, Ctenocephalides felis on cats for up to four weeks.

Testing Laboratory: Institute for Parasitology, Hannover Veterinary School, Hannover,Germany and Bahrs Hill Research Station, Beenleigh, Queensland, Australia

IPM: Not appropriate

Testing procedure:

Approximately 100 laboratory reared, unfed adult C. felis fleas were placed along the dorsal midline (over the sacrum) of each cat. Infestations were carried out 15, 12, 7, 5, and 1 day before treatment, and 6, 13, 20, and 27 days after treatment.

Twenty cats infested with cat fleas were each randomly placed in one of two groups to be treated or left untreated. Ten mg/kg w/v Bayer 7391 (imidacloprid) was placed on the midline of the top of the neck of each cat in the treatment group.

Immediately before treatment, one day after treatment, and one day after each reinfestation, total flea counts were conducted on each cat while under sedation. Efficacy was calculated to determine percent reduction of the flea population.

During the trial each cat was kept in an individual cage with one half of the flooring made of stainless steel mesh to allow flea eggs to drop through and be collected. The apertures were 2.3 x 2.2 mm made with 1.0 gauge wire. A galvanized egg collection tray was placed under each cage for two hours at each observation period. During this period the cats were restrained to the portions of the cages with mesh flooring. Flea eggs were collected four days before treatment and 2, 9, 16, 23, and 30 days after treatment.

Aliquots of eggs and debris from each cage were evenly sprinkled over the surface of a glass petri dish and the eggs were counted using a 10x stereomicroscope. Nonviable eggs which were brown, desiccated, shriveled, or a larva had eclosed were not counted.

All cats were kept under observation for abnormal behavior for one hour after treatment and checked 24 hours after treatment and 7, 14, 21, and 28 days after treatment.

Results:

Reductions of flea populations compared to populations on untreated cats one day after reinfestations were made were 99.5%, 99.1%, 96.9%, 96.6%, and 95.7% respectively 1, 7, 14, 21, and 28 days after treatment. Reduction of egg production was 98.5%, 100%, 99.9%, 99.9%, and 97.8% respectively for counts made 2, 9, 16, 23, and 30 days after treatment.

There was no evidence of intoxication, injury or irritation to any of the treated animals.

Field trials:

In controlled field trials on the degree of efficacy and tolerance to a spot-on 10% formulation Bayer NTN 33893 was field tested on domestic cats in Germany using 10 mg of 10% imidacloprid per Kg body weight.

Twenty seven cats naturally infested with cat fleas were treated by placing 10% imidacloprid in a spot on the back of the neck. The cats were from households in Lower Saxony, Bavaria, and Rhineland-Palatine.

A semiquantitative method of flea counting was used. The number of fleas in the fur of cats was grouped as (0) when no fleas were seen, as (1) when 1 to 5 fleas were found, as (2) when five to ten fleas were found, and (3) when more than ten fleas were found. Flea assessment was made before treatment (day 0), 24 hours post-treatment, and 7, 14, 21, 28 days after treatment.

Control of adult cat fleas was evident with all 27 cats treated. The onset of activity could be as early as 12 hours after treatment. No fleas were found on any of the cats one day or seven days after treatment. Fourteen days after treatment one cat had a light infestation, 21 days after treatment six cats had light infestations and 28 days after treatment seven cats had light infestations.

On the basis of data presented, 10mg imidacloprid /kg body weight appears to be very effective against cat fleas. While flea control on cats treated in the field was not as good as in laboratory studies, with a few fleas observed on some cats starting 14 days after treatment, efficacy was acceptable even though the animals remained in the environments where they had become infested with fleas.

The report stated that "Local and general tolerance of the product and formulation was highly satisfactory." No skin intolerance was noted through four weeks of observation. Reportedly some of the tests were located in areas where a certain degree of resistance against organophosphates and pyrethroids had been reported.

The author stated that differences in duration of efficacy may be due to different behavior in grooming, differences in the hair coat, and differences in population dynamics of fleas in different localities at a given time.

In earlier studies, MRID 436795-03, page 12 of 32 (Miles report no. 74571), transient salivation was observed shortly after treatment, including one cat treated with blank vehicle. One of the cats vomited. The author stated that no other adverse reactions occurred, and that salivation occurred only within five hours of treatment. It should be ascertained that the component(s) with emetic properties was not included in the formulation used in more recent testing and will not be in the commercial product.

Conclusion (efficacy)-The data in these two reports support the claim that 10 mg of 10% imidacloprid per kg body weight will control cat fleas for up to four weeks.