

Date of Index Listing: February 23, 2015

FREEDOM OF INFORMATION SUMMARY

ORIGINAL REQUEST FOR ADDITION TO THE INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL
DRUGS FOR MINOR SPECIES

MIF 900-011

F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE
(benzalkonium chloride, polyhexanide and cypermethrin topical ointment)

Raptors, Pet Birds, Captive Small Mammals, Captive Reptiles, and
Captive Exotic/Zoo Mammals

“For use as a topical antiseptic for surface wounds, to repel flies, and to treat
infestations due to fly strike in raptors, pet birds, captive small mammals,
captive reptiles, and captive exotic/zoo mammals.”

Requested by:

Health and Hygiene (Pty) Ltd

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I. GENERAL INFORMATION:

- A. File Number:** MIF 900-011
- B. Requestor:** Health and Hygiene (Pty) Ltd
P.O. Box 906
Florida Hills, 1716, South Africa
- U.S. Agent:
Kristen V. Khanna, PhD, MBA
Animal Clinical Investigation, LLC
4926 Wisconsin Ave, NW
Washington, D.C. 20016
- C. Proprietary Name(s):** F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE
- D. Established Name(s):** Benzalkonium chloride, polyhexanide and cypermethrin topical ointment
- E. Pharmacological Category:** Antimicrobial and Insecticide
- F. Dosage Form(s):** Topical ointment
- G. Amount of Active Ingredient(s):** 0.405 g benzalkonium chloride and 0.03 g polyhexanide/100 mL and 0.25 g cypermethrin/100 g
- H. How Supplied:** 25 g tubes and 100 g and 500 g plastic jars
- I. How Dispensed:** Over-the-Counter (OTC)
- J. Dosage(s):** Applied topically to wound site
- K. Route(s) of Administration:** Topical
- L. Species/Class(es):** Raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals (use is prohibited in food-producing species such as rabbits, deer, ducks, pigeons, and turtles)
- M. Indication(s):** For use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals.

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY:

In accordance with 21 CFR part 516, a qualified expert panel evaluated the target animal safety and effectiveness of F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE, for use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals, to determine whether the benefits of using F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE for the proposed uses outweigh its risks to the target animals. The members of the qualified expert panel were:

David Sanchez-Migallon Guzman, LV, MS, Diplomate ECZM (Avian), Diplomate ACZM;

Neil A. Forbes, BVetMed, Diplomate ECZM (Avian), FRCVS;

Michelle Barrow, BSc, BVMS ZooMed (Avian), PF Cert Conservation Medicine MRCVS;

Michael Stanford, BVSc, FRCVS; and

Jaime Samour, MVZ, PhD, Diplomate ECZM (Avian).

A. FINDINGS OF THE QUALIFIED EXPERT PANEL:

Based on a thorough review of the literature, data from laboratory studies, and their own personal experience, the qualified expert panel concluded that F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE is both effective and safe for the following uses:

For use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals.

Benzalkonium chloride is a nitrogenous cationic surface-acting agent belonging to the quaternary ammonium group. Polyhexanide, also known as PHMB and hexamethylene biguanide, is a cationic biocide. Benzalkonium chloride and polyhexanide are used in a number of common household products such as face and hand washes and as an all-purpose cleaner and disinfectant, respectively.

Cypermethrin is a synthetic pyrethroid insecticide used for control of agricultural insect pests, as spot treatment to control insect pests in houses, and as an insect repellent for animals.

In order to assess the safety F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE, the qualified expert panel performed a review of six laboratory toxicology studies, available literature, and their own experience using the drug. Laboratory studies reviewed by the expert panel included: acute oral toxicity in rats, acute dermal toxicity in rats, acute dermal irritation in guinea pigs, acute sensitization in guinea pigs, acute inhalation toxicity in rats, and acute eye irritation in rabbits. These studies were conducted with the three active ingredients (benzalkonium chloride, polyhexanide, and cypermethrin) in solution form.

The LD50 after oral dosing in rats was between 2000 and 5000 mg/kg, which the panel calculated to be a dose of 27-67 g of F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE per kg bodyweight.

In the acute inhalation toxicity study, rats were dosed with >2 mg/L air for 4 hours. Mild respiratory distress was seen initially but resolved after the first hour of dosing, and no gross findings were found at necropsy.

In the acute dermal irritation study, a 6 cm² area of skin was shaved on three guinea pigs. The drug was applied to the shaved area and remained in contact with the skin for 4 hours. Two of the three study animals had mild erythema at the application site at the end of the dosing period. The erythema resolved in both animals within 24 hours after dosing without any treatment.

The acute eye irritation study was conducted in three New Zealand white rabbits. The drug was applied to the right eye of each rabbit. After one hour of contact, mild swelling and eversion of the eyelids was noted in the treated eyes. These signs decreased within 24 hours after dosing and resolved in all animals within 72 hours after dosing without treatment.

Results of the acute dermal toxicity and acute sensitization studies were negative.

The expert panel stated in their report that they have used F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE extensively in practice. They have administered the drug by external dermal application and applied it directly into open wounds without adverse reactions.

To determine the effectiveness of F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE for the proposed intended uses, the expert panel performed a review of available literature, in vitro laboratory studies, and their own personal experience administering the drug. The antimicrobial mechanism of action of F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE is disruption of the cell membrane causing loss of essential cell components. As part of their determination of effectiveness, the expert panel considered the need for both of the antimicrobial active ingredients (benzalkonium chloride and polyhexanide) in the drug formulation. The panel states that studies have shown that benzalkonium chloride and polyhexanide function more efficiently in different environments. The two active ingredients are more effective and have a larger spectrum of activity when administered in combination rather than individually (Brown, 2008; Wattanaphansak et al., 2010).

Laboratory studies reviewed by the expert panel include in vitro bactericidal, fungicidal, virucidal, and sporicidal tests to support antimicrobial activity and in vitro studies with adult and larval *Lucilia cuprina*, commonly known as the Australian sheep blowfly, to support insecticidal activity. The in vitro antimicrobial studies were conducted with a separate product marketed by the requestor which contains only benzalkonium chloride and polyhexanide as the active ingredients in solution form. The tests were conducted to support registration of this product by the U.S. Environmental Protection Agency (EPA). An acceptable reduction in microbial counts was achieved in all tests and the

product is registered by the EPA as a disinfectant at a concentration of 0.0216% benzalkonium chloride and 0.0016% polyhexanide.

The in vitro insecticidal studies reviewed by the panel were a South African Bureau of Standards (SABS) knockdown study with adult *L. cuprina* and a second study to determine the effectiveness of the product against larval *L. cuprina*. Both of these studies were conducted with F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE. In the knockdown study, 100 % mortality was achieved against adult flies. In the larval study, 97.6% mortality was achieved with the remaining 2.4% of larvae considered moribund after exposure to the drug.

The expert panel report contains multiple examples of successful uses of the drug either provided in literature or when administered by the expert panel members themselves. They list a multitude of species which have received topical application of the drug to treat dermal wounds, abrasions, puncture wounds, maggot infestations, and fly strike wounds (myiasis). Some of the species listed are psittacines (pedal and axillary skin infections), passerines (axillary skin infections), captive non-food-producing minor species hoof stock (dart wounds and second intention wound healing), non-human primates (dart, bite, and miscellaneous trauma wounds), elephants (dart wounds, abscesses, and second intention wound healing), hyena (bite wounds), snakes (second intention wound healing and cutaneous burns), and lizards (bite wounds, abscesses, and second intention wound healing).

The expert panel states that F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE is of particular benefit when treating non-domesticated zoological and wildlife patients because daily wound management is dangerous and impractical with these animals. The drug is of particular benefit during warmer seasons when flies are present, because most of these animals live in outdoor enclosures where flies can come in contact the wound site. Panel members have had success in treating surface wounds and myiasis in animals with only once weekly application of F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE. The expert panel further states that, collectively, they have successfully treated hundreds of animals with F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE.

B. LITERATURE CONSIDERED BY THE QUALIFIED EXPERT PANEL:

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22. Forbes, N.A. (2006). Pet parrots day course. Great Western Referrals. Swindon, UK. (course notes).
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III. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE:

"Not for use in humans. Keep out of reach of children. Do not contaminate food, water, eating utensils, or food contact surfaces. Wash hands before eating or drinking. If accidentally ingested, contact a Poison Control Center or a doctor. Do not induce vomiting unless advised by the Poison Control Center or a doctor. If accidental eye contact, hold eye open and rinse with water for 10 minutes. Seek medical help if necessary."

IV. AGENCY CONCLUSIONS:

The information submitted in support of this request for F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE for addition to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (Index) for the following intended uses satisfies the requirements of section 572 of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 516:

For use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals.

A. DETERMINATION OF ELIGIBILITY FOR INDEXING:

As part of the determination of eligibility for inclusion in the Index, FDA determined that the drug for these intended uses was safe to the user, did not

individually or cumulatively have a significant effect on the human environment, and that the description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new animal drug was sufficient to demonstrate that the requestor has established appropriate specifications for the manufacture of the new animal drug. Additionally, the requestor has committed to manufacture the drug in accordance with current good manufacturing practices (cGMP).

The Index is only available for new animal drugs intended for use in minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals and for new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 512(d) of the act. Because this new animal drug is not intended for use in food-producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for granting this request for addition to the Index.

Due to the broad range of species included in the intended uses, FDA determined that labeling language was necessary to prevent potential use in major species and in food-producing species. The following two statements were added to the labeling:

“Use of this product is prohibited in dogs, cats, and horses and in food-producing species such as cattle, pigs, chickens, turkeys, rabbits, deer, ducks, pigeons, and turtles.”

“Use only when there is a reasonable certainty that the treated animal will not be consumed by humans or food-producing animals.”

B. QUALIFIED EXPERT PANEL:

The qualified expert panel for F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE met the selection criteria listed in 21 CFR 516.141(b). The panel satisfactorily completed its responsibilities in accordance with 21 CFR part 516 in determining the target animal safety and effectiveness of F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE for use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals.

C. MARKETING STATUS:

F10 brand ANTISEPTIC BARRIER OINTMENT WITH INSECTICIDE will be marketed over-the-counter.

D. EXCLUSIVITY:

Products listed in the Index do not qualify for exclusive marketing rights.

E. ATTACHMENTS:

Facsimile Labeling:

25 g tube, 100 g jar, and 500 g jar