

Date of Index Listing: February 6, 2015

FREEDOM OF INFORMATION SUMMARY

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

MIF 900-007

F10 brand ANTISEPTIC SOLUTION

(benzalkonium chloride and polyhexanide topical solution)

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

"For the treatment and control of upper and lower respiratory tract disease associated with bacterial, fungal, or viral organisms susceptible to benzalkonium chloride and polyhexanide in raptors, pet birds, captive small mammals, and captive reptiles."

and

"For use as a topical antiseptic for surface wounds on 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 900-007
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 SOLUTION
D. Established Name(s):	Benzalkonium chloride and polyhexanide topical solution
E. Pharmacological Category:	Antimicrobial
F. Dosage Form(s):	Topical solution
G. Amount of Active Ingredient(s):	0.22 mg benzalkonium chloride and 0.02 mg polyhexanide/mL
H. How Supplied:	200 mL bottles of concentrated solution that must be diluted 1:250 with normal saline before use and 1 L bottles of ready-to-use solution
I. How Dispensed:	By veterinary prescription (Rx)
J. Dosage(s):	Applied topically, by nebulization, or by nasal flushing at a concentration of 0.22 mg benzalkonium chloride and 0.02 mg polyhexanide per mL of solution
K. Route(s) of Administration:	Topical, intranasal, and inhalation
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 the treatment and control of upper and lower respiratory tract disease associated with bacterial, fungal, or viral organisms

susceptible to benzalkonium chloride and polyhexanide in raptors, pet birds, captive small mammals, and captive reptiles.

For use as a topical antiseptic for surface wounds on 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 SOLUTION, for the treatment and control of respiratory tract disease and for use as a topical antiseptic for surface wounds, to determine whether the benefits of using F10 brand ANTISEPTIC SOLUTION for the proposed use 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 SOLUTION is both effective and safe for the following uses:

For the treatment and control of upper and lower respiratory tract disease associated with bacterial, fungal, or viral organisms susceptible to benzalkonium chloride and polyhexanide in raptors, pet birds, captive small mammals, and captive reptiles; and

For use as a topical antiseptic for surface wounds on 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.

In order to assess the safety F10 brand ANTISEPTIC SOLUTION, 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. The LD50 after oral dosing in rats was between 2000 and 5000 mg/kg, which the panel calculated to be a lethal dose of 9.3-23.2 L of the ready-to-use solution (0.22 mg benzalkonium chloride and 0.02 mg polyhexanide per mL solution) per kg bodyweight. In the acute inhalation toxicity study, rats were dosed with >2mg/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. Results of the acute dermal toxicity, acute dermal irritation, acute sensitization, and acute eye irritation studies were negative.

The expert panel provided multiple examples of how they have personally administered F10 brand ANTISEPTIC SOLUTION. Panel members have dosed the drug topically, by nasal flushing, and by nebulization. Some of the species treated include: raptors, psittacines, rodents, non-human primates, tortoises, badgers, and foxes. As a group, the panel has over 15 years of experience using F10 brand ANTISEPTIC SOLUTION. In that time, they have not experienced any adverse reactions when the drug is used at the recommended dilution of 0.22 mg benzalkonium chloride and 0.02 mg polyhexanide per mL of solution.

To determine the effectiveness of F10 brand ANTISEPTIC SOLUTION 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 mechanism of action of F10 brand ANTISEPTIC SOLUTION 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 active ingredients 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. These studies were conducted to support registration of the 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 surface disinfectant at a concentration of 0.0216% benzalkonium chloride and 0.0016% polyhexanide.

The expert panel report also contains a discussion of clinical conditions successfully treated with F10 brand ANTISEPTIC SOLUTION based on information found in the literature and personal experience of the expert panel members administering the drug to the target animals. Examples included are:

- treatment and control of respiratory disease associated with fungal and bacterial organisms in birds
- treatment of bacterial sinusitis in birds

- treatment of respiratory disease associated with bacterial organisms in small mammals
- treatment of bacterial and fungal dermatitis in small mammals
- treatment of respiratory disease associated with bacterial and viral organisms in reptiles

The expert panel states that they have collectively treated hundreds of birds, small/exotic mammals, and reptiles with F10 brand ANTISEPTIC SOLUTION and had good clinical outcomes.

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 SOLUTION:

"Not for use in humans. Keep out of reach of children. If accidentally ingested, do not induce vomiting. Give milk or water to drink. 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 SOLUTION 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 the treatment and control of upper and lower respiratory tract disease associated with bacterial, fungal, or viral organisms susceptible to benzalkonium chloride and polyhexanide in raptors, pet birds, captive small mammals, and captive reptiles; and

For use as a topical antiseptic for surface wounds on 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 SOLUTION 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 SOLUTION for the treatment and control of upper and lower respiratory tract disease associated with bacterial, fungal, or viral organisms susceptible to benzalkonium chloride and polyhexanide in raptors, pet birds, captive small mammals, and captive reptiles and for use as a topical antiseptic for surface wounds on raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals.

C. MARKETING STATUS:

F10 brand ANTISEPTIC SOLUTION is restricted to use by or on the order of a licensed veterinarian.

D. EXCLUSIVITY:

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

E. ATTACHMENTS:

Facsimile Labeling:

200 mL bottle of concentrate and 1L bottle of ready-to-use solution

