Date of Authorization: April 24, 2026
(As revised June 22, 2026)

FREEDOM OF INFORMATION (FOI) SUMMARY

Emergency Use Authorization (EUA)

EUA 006677

F10® Antiseptic Barrier Ointment with Insecticide

(benzalkonium chloride, polyhexanide and cypermethrin topical ointment)

Topical Ointment

cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive and captured wild, exotic, and zoo mammals

Scope of Authorization:
For the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive and captured wild, exotic, and zoo mammals.

Sponsored by:

Health and Hygiene (Pty) Ltd

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I. GENERAL INFORMATION

A. File Number

EUA 006677

B. Sponsor

Health and Hygiene (Pty) Ltd
PO Box 906
Florida Hills, Gauteng, 1716, South Africa

U.S. Agent Name and Address:

Kristen Khanna, PhD, MBA
CEO
Animal Clinical Investigation, LLC
4445 Willard Ave
Sixth Floor
Chevy Chase, MD 20815

C. Proprietary Name

F10® Antiseptic Barrier Ointment with Insecticide

D. Drug Product Established Name

benzalkonium chloride, polyhexanide and cypermethrin topical ointment

E. Pharmacological Category

Ectoparasiticide and antiseptic

F. Dosage Form

Topical ointment

G. Amount of Active Ingredient

Benzalkonium chloride 0.405 g/100 mL, polyhexanide 0.03 g/100 mL, and cypermethrin 0.25 g/100 g

H. How Supplied

3.5 oz (100 g) and 17.6 oz (500 g) jars

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

Use disposable gloves during application and wash hands thoroughly after use. Clean the wound prior to application. Apply a layer of ointment over the entire wound site. Repeat once a week, if necessary or as advised by your veterinarian.

This product is water soluble and should be reapplied if animal is bathed or exposed to rain. If the wound persists or worsens, contact your veterinarian.

K. Route of Administration

Topical ointment

L. Species/Classes

Cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive and captured[1] wild, exotic, and zoo mammals

M. Food and Drug Administration (FDA) Indexed Product Indication

F10® Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) is indexed 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 (Minor Species Index File (MIF) 900-011).[2]

N. Emergency Authorized Uses

For the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle, horses, minor species[3] of hoof stock, raptors and other wild birds, pet birds, and captive and captured wild, exotic, and zoo mammals.

O. Limitations of Authorized Use

It is a violation of federal law to use this drug product other than as directed in the Fact Sheet.

Cattle, goats, and sheep must not be slaughtered for human consumption within 30 days of treatment.

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[1] Definitions for “captive wildlife” and “captured wildlife” can be found in the last section of the USDA APHIS New World Screwworm Response Playbook, accessible at https://www.aphis.usda.gov/animal-emergencies/nws.
[2] See FDA’s webpage “The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species” at https://www.fda.gov/animal-veterinary/minor-useminor-species/index-legally-marketed-unapproved-new-animal-drugs-minor-species
[3] Minor species are all animals, other than humans, that are not one of the major species. They include animals such as zoo animals, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include sheep, goats, and game birds, among others. The term ‘major species’ means cattle, horses, swine, chickens, turkeys, dogs, and cats.

For non-domesticated minor species hoof stock,[4] use only when there is a reasonable certainty that the treated animal will not be slaughtered or harvested for human consumption within 30 days of treatment.

Milk taken from cows, goats, or sheep during treatment and for 10 days after treatment must not be used for human consumption.

A withdrawal period has not been established for this product in pre-ruminating calves. Treated calves and calves born to treated cows must not be processed for veal.

Do not use in horses intended for human consumption.

Do not use in domestic dogs and cats.

Do not use in food-producing species that have not been assigned a withdrawal period, as listed in the Withdrawal Periods and Residue Warnings section of the Fact Sheet.

F10® Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of F10® Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

P. Effect of EUA Revision

Following the authorization of EUA 006677 on April 24, 2026, CVM received several questions about the term “captive” and whether it included target animals that were temporarily held, treated, and then released. To minimize confusion and clarify the intended target animal population, CVM determined that the indication should be revised to clarify that animals that are treated and released are included in the target animal population. This was achieved by adding “and captured” to the “captive wild, exotic, and zoo mammals” part of the indication. FDA adopted the USDA APHIS definitions for “captive wildlife” and “captured wildlife” from their New World Screwworm Response Playbook. Captive wildlife are animals maintained in captivity for exhibition (including zoos), sale, personal use, education, propagation, preservation, protection or hunting purposes with no expectation of returning to, or allowing to move freely in, the wild. Captured wildlife are free-ranging wildlife that are under temporary human control with the intent to be returned to and move freely in the wild.

[4] For example, deer, elk, antelope, and nilgai.

II. EFFECTIVENESS

A. Dosage Regimen

This EUA does not change the dosage regimen in the previously indexed drug product.

B. Information Supporting Emergency Use Authorization

In accordance with Section 564 of the FD&C Act, the sponsor provided information to support that F10® Antiseptic Barrier Ointment with Insecticide may be effective for the prevention and treatment of infestations caused by New World screwworm (NWS; *Cochliomyia hominivorax*) larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive and captured wild, exotic, and zoo mammals. This submission includes information submitted in support of indexing F10® Antiseptic Barrier Ointment with Insecticide under MIF 900-011, information submitted for this EUA, and publicly available information.

Information to support the effectiveness of the addition of F10® Antiseptic Barrier Ointment with Insecticide under MIF 900-011 were primarily conducted using blowfly species common in South Africa, including *Lucilia cuprina*. See the FOI Summary for MIF 900-011 dated February 23, 2015.

Cypermethrin has documented activity against several fly species, including other fly species which are known to cause myiasis in mammals. Additionally, the indexed product is labeled for use as a topical antiseptic for surface wounds; this condition of use would also apply when used in cases of NWS myiasis, reducing the risk of secondary infection. Therefore, F10® Antiseptic Barrier Ointment with Insecticide, which contains cypermethrin as an insecticide ingredient, may be effective for the prevention and treatment of *Cochliomyia hominivorax* myiasis when applied to wounds (prevention) or sites of myiasis (treatment).

III. TARGET ANIMAL SAFETY

FDA did not require target animal safety studies for this authorization. The FOI Summary for F10® Antiseptic Barrier Ointment with Insecticide (MIF 900-011) dated February 23, 2015, contains a summary of the target animal safety conclusions for use of F10® Antiseptic Barrier Ointment with Insecticide 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.

The indexed product has been used outside the U.S. in cattle and numerous minor species of cloven-hoofed (ungulate) mammals such as sheep, goats, deer, buffalo, bison, and antelope without reports of adverse events. The insecticide component in this ointment, cypermethrin, is contained in several products registered by the U.S. Environmental Protection Agency (EPA) for use on horses. These products are widely used on horses in the U.S. without serious safety concerns. Potential adverse reactions include hypersensitivity reactions (including urticaria and pruritus) and hair loss. The benefits in horses of using F10® Antiseptic Barrier Ointment with Insecticide, which contains cypermethrin, outweighs these risks because myiasis is a potentially deadly disease.

The product is currently indexed for raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals when there is a reasonable certainty that the treated animal will not be consumed by humans or food-producing animals. It is reasonable to include these target animals on the Fact Sheet for this EUA; however, captive reptiles are not susceptible to NWS; therefore, they were not included in the list of target species for NWS.

IV. HUMAN FOOD SAFETY

The human food safety assessment for F10® Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) was based on publicly available information, with the following as the main sources:

1. U.S. Environmental Protection Agency. (2006, August 10). Toxicology disciplinary chapter for the re-registration eligibility decision (RED) risk assessment: Alkyl dimethyl benzyl ammonium chloride (ADBAC)* [Memorandum].
   *Benzalkonium chloride is also called ADBAC.

2. U.S. Environmental Protection Agency. (2008, January 9). Poly (hexamethylene biguanide) hydrochloride (PHMB)*; Exemption from the requirement of a tolerance. Final rule. Federal Register, 73(6), 1512. 40 CFR Part 180. EPA-HQ-OPP-2005-0268; FRL-8345-8.
   *Polyhexanide is also called PHMB.

3. World Health Organization. (2004). Cypermethrin and alpha-cypermethrin. WHO Food Additives Series, 53.

4. U.S. Environmental Protection Agency. (2025, July 17). Cypermethrin; Pesticide tolerances. Final rule. Federal Register, 90(135). 40 CFR Part 180. EPA-HQ-OPP-2024-0220; FRL-12817-01-OCSPP.

5. Food and Agriculture Organization (FAO) of the United Nations (1997). Cypermethrin and Alpha-cypermethrin. Residues of some veterinary drugs in animals and foods. FAO Food and Nutrition Paper 41/9.

6. FAO (2002). Cypermethrin and Alpha-cypermethrin. Residues of some veterinary drugs in animals and foods. FAO Food and Nutrition Paper 41/14.

7. FAO (2004). Alpha-cypermethrin and cypermethrin. Residues of some veterinary drugs in animals and foods. FAO Food and Nutrition Paper 41/16.

FDA concluded that the food products obtained from treated animals are safe for human consumption when the conditions of use authorized by the EUA are followed, including the withdrawal period and milk discard time.

For cattle, goats, and sheep, a 30-day withdrawal period and 10-day milk discard time are assigned.

For non-domesticated minor species hoof stock, use only when there is a reasonable certainty that the treated animal will not be slaughtered or harvested for human consumption within 30 days of treatment.

A withdrawal period has not been established for this product in pre-ruminating calves. Treated calves and calves born to treated cows must not be processed for veal.

V. USER SAFETY

The product Fact Sheet contains the following information regarding safety to humans handling, administering, or exposed to F10® Antiseptic Barrier Ointment with Insecticide:

Not for use in humans. Keep out of reach of children.

Do not use with soaps or other chemicals.

Use disposable gloves during application and wash hands thoroughly after use. 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 occurs, hold eye open and rinse with water for 10 minutes. Seek medical help if necessary.

VI. AGENCY CONCLUSIONS

Based on the totality of scientific evidence available to FDA, including information submitted in support of the Minor Species Index File (MIF 900-011) and this EUA, as well as publicly available information, it is reasonable to believe that F10® Antiseptic Barrier Ointment with Insecticide, when used as authorized, may be effective for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive and captured wild, exotic, and zoo mammals; and that the known and potential benefits of F10® Antiseptic Barrier Ointment with Insecticide outweigh the known and potential risks. New World screwworm infestations can have significant adverse health consequences and can be fatal if left untreated due to the extensive tissue damage caused by *Cochliomyia hominivorax* larvae. The benefit of preventing or treating this potentially fatal disease outweighs the health risks of using this product in these species. Additionally, it was concluded that residues in food products derived from cattle, goats, and sheep treated with F10® Antiseptic Barrier Ointment with Insecticide will not represent a public health concern when the product is used as authorized.

There is no adequate, approved,[5] and available alternative to the product for the prevention and treatment of NWS (myiasis) in these species. There are no approved products for horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive and captured wild, exotic, and zoo mammals. Although there are conditionally approved products for the prevention and treatment of NWS in cattle, F10®

[5] "Approved" products include conditionally approved products for purposes of EUAs issued under Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.

Antiseptic Barrier Ointment with Insecticide provides a distinct option for treating and preventing NWS in cattle because it is a topical ointment product that is applied locally, directly to wounds. Cattle and other hoof stock are at particular risk of infestation by NWS, and a diverse and sufficient supply of products is needed to adequately address an incursion in the United States.

For additional information on all products authorized or conditionally approved for use to treat and/or prevent New World screwworm, please see FDA's "New World Screwworm: Information for Veterinarians" webpage at https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians.

A. Duration of Authorization: Revision and Revocation

This EUA will be effective until revoked under Section 564(g) of the FD&C Act or until the Secretary's declaration of emergency or threat justifying emergency authorized use is terminated (Section 564(f)(1)), with exception for continued use permissible under Section 564(f)(2). FDA may revoke or revise this authorization if emergency use of this animal drug for NWS myiasis is no longer justified, if the product no longer meets the criteria for issuance of an EUA under Section 564(c) of the FD&C Act, or other circumstances make such revision or revocation of the authorization appropriate to protect the public health or safety (Section 564(g)(2) of the FD&C Act).

B. Marketing Status

This product is authorized to be marketed OTC because the authorized labeling contains adequate directions for use by laypersons and the conditions of use prescribed on the label are reasonably certain to be followed in practice.