Date of Authorization: August 7, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006723

CLiK™ Extra

(dicyclanil topical suspension)

wound spray

Topical suspension

Sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn

Scope of Authorization: For application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn.

Sponsored by:

Elanco US Inc.

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I. GENERAL INFORMATION

A. File Number

EUA 006723

B. Sponsor

Elanco US Inc.
450 Elanco Circle
Indianapolis, IN 46221

Drug Labeler Code: 058198

C. Proprietary Name

CLiK™ Extra

D. Drug Product Established Name

dicyclanil topical suspension

E. Pharmacological Category

Insect growth regulator

F. Dosage Form

Topical suspension

G. Amount of Active Ingredient

65 mg dicyclanil/mL

H. How Supplied

0.8 and 2.2 L bottles

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

Apply on or around wound(s). Use the following dosing table for maximum volume per animal based on body weight. If there are multiple wounds on a single animal, divide the total volume across all wounds as necessary. Small wounds may not need the total volume.

Bodyweight (kg)	Total volume/animal (mL)
10 – 20	Up to 20
21 – 30	Up to 24
31 – 50	Up to 30
> 50	Up to 36

K. Route of Administration

Topical spray

L. Species/Class

Sheep, cattle, goats, swine, camelids, and the following captive and captured[1] wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn

M. Emergency Authorized Use

For application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn.

N. Limitations of Authorized Use

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

Sheep, cattle, goats, swine, cervids, American bison, and bighorn sheep must not be slaughtered or harvested for human consumption within 86 days of treatment.

For captured cervids, captured American bison, and captured bighorn sheep, use only when there is a reasonable certainty that the treated animal will not be slaughtered or harvested for human consumption within 86 days of treatment.

Treated Sonoran pronghorn and camelids may not be used for human consumption.

A milk discard time has not been established for this product. Do not use in animals producing milk 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.

CLiK™ Extra (dicyclanil topical suspension) wound spray is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of CLiK™ Extra (dicyclanil topical suspension) wound spray under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act

[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

(FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

II. EFFECTIVENESS

A. Evidence Supporting Emergency Use Authorization

In accordance with Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the sponsor provided information to support that it is reasonable to believe that CLiK™ Extra may be effective for application on or around wounds for the prevention of infestations caused by New World screwworm (NWS, *Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn based on data from foreign approvals, dose determination studies, and scientific literature. The evidence supporting effectiveness is based on one study in the scientific literature from Uruguay in 2012 against NWS in sheep, two dose determination studies in 2016 in Brazil against NWS in cattle, and two studies in the scientific literature against NWS in cattle from Uruguay in 2012 and Argentina in 1996. Collectively, the data support that it is reasonable to believe that CLiK™ Extra may be effective for application on or around wounds for the prevention of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in sheep and cattle. It was concluded it is reasonable to believe that effectiveness will be similar in target species other than sheep and cattle, e.g., goats, swine, camelids, cervids, American bison, bighorn sheep, and Sonoran pronghorn, based on the topical administration and local site of action of this drug.

1. Literature in Sheep

   Morlán, B., & Bonino Leaniz, J. A. (2013). Evaluation of the preventive action of dicyclanil 5% (CLiK) against cutaneous myiasis caused by *Cochliomyia hominivorax* in ruminants under natural field conditions.

   A study conducted in Uruguay in 2012 to 2013 evaluated the effectiveness of a single topical application of dicyclanil topical suspension at a concentration of 50 mg/mL (5%) and a volume of 20 mL per lamb for the prevention of natural infestations of NWS following tail docking. There were 15 lambs in each group. Dicyclanil topical suspension was applied directly to the wound after the procedure in the treated lambs. The control lambs did not receive any wound treatment. All animals were evaluated twice daily for 18 days for myiasis. The study reports by Day 13, 8 of the 15 control lambs had myiasis. No lambs that received dicyclanil topical suspension had myiasis at any point during the study.

   This report was available in Spanish with very limited information. However, it demonstrates that dicyclanil topical suspension at a 50 mg/mL concentration applied directly on a surgical wound at a volume of 20 mL was effective in preventing NWS myiasis in sheep. It was therefore concluded that dicyclanil topical suspension at a 65 mg/mL concentration applied directly on a surgical wound may be effective in preventing NWS myiasis in sheep.

2. Dose determination studies in cattle

Two dose determination studies were conducted in 2016 in Brazil in cattle utilizing natural NWS infestations.

The first study enrolled 10 animals in each group; two concentrations (1.25% and 5% dicyclanil topical suspension) were evaluated as were four volumes (5, 10, 15, and 20 mL) per wound. There was also a negative control group. Two circular wounds were created on each animal, one wound on the neck and one on the rump on Day 0. Animals were then continuously exposed to natural NWS infestation and observed for 30 days. If scabbing/healing began, scabs were removed. All control animals had myiasis by Day 10. None of the ten animals that received 20 mL of the 5% dicyclanil topical suspension concentration had myiasis up to and including Day 10.

The second study enrolled 15 animals in each group; two concentrations (1.25% and 5% dicyclanil topical suspension) were evaluated. Animals received either 6 or 16 mL of the 1.25% concentration or 16 mL of the 5% concentration. There was also a negative control group. Animals were surgically castrated, had dicyclanil topical suspension applied to the wound, and then were continuously exposed to natural NWS infestation for 30 days. Animals were observed daily to Day 19, then once on Days 21, 26, and 30. By Day 8, all control animals had myiasis. On Day 8, one of the 15 animals that received 16 mL of the 5% concentration had myiasis. By Day 30, three of the 15 animals that received 16 mL of the 5% concentration had myiasis.

Together, these two dose determination studies demonstrate that dicyclanil topical suspension at a 50 mg/mL concentration applied directly on a surgical wound at a volume of 16 to 20 mL was effective in preventing NWS myiasis in cattle. It was therefore concluded that dicyclanil topical suspension at a 65 mg/mL concentration applied directly on a surgical wound may be effective in preventing NWS myiasis in cattle.

3. Literature in cattle

Anziani, O., Guglielmone, A. A., & Schmid, H. (1998). Efficacy of dicyclanil in the prevention of screwworm infestation (*Cochliomyia hominivorax*) in cattle castration wounds. *Veterinary Parasitology,* 76(3), 229-232.

A study conducted in Argentina in 1996 evaluated the effectiveness of a single topical application of 50 mg/mL dicyclanil topical suspension at a volume of 20 mL per steer for the prevention of natural infestations caused by NWS following surgical castration. Dicyclanil topical suspension was applied directly to the wound after the procedure. The control steers did not receive any wound treatment. There were 20 animals in each group. All animals were evaluated for myiasis on Days 4, 8, 12, 16, 19, 23, and 25 after castration. By Day 25, 16 out of the 20 controls had myiasis and one treated animal had myiasis, which occurred on Day 19.

Morlán, B., & Bonino Leaniz, J. A. (2013). Evaluation of the preventive action of dicyclanil 5% (CLiK) against cutaneous myiasis caused by *Cochliomyia hominivorax* in ruminants under natural field conditions.

This is the same study conducted in Uruguay described above. The study conducted both a lamb and a cattle trial. For cattle, a single topical application of 5% dicyclanil topical suspension at a total volume of 30 mL (15 mL in scrotal sac, 15 mL in periscrotal area) per calf was evaluated for its effectiveness in the prevention of natural infestations caused by NWS following surgical castration. There were seven treated steers and six negative controls. All animals were evaluated twice daily for 15 days. No treated steers were reported with myiasis. Only one control animal was reported with myiasis on Day 6.

Anziani 1998 demonstrates that dicyclanil topical suspension at a 50 mg/mL concentration applied directly on a surgical wound at a volume of 20 mL was effective in preventing NWS myiasis in cattle. It was therefore concluded that dicyclanil topical suspension at a 65 mg/mL concentration applied directly on a surgical wound may be effective in preventing NWS myiasis in cattle. One major limitation in the Morlán 2013 study was that there was insufficient infestation pressure in the control group (e.g., one out of six controls with myiasis). However, taken together, the two papers provide sufficient evidence that a 65 mg/mL dicyclanil topical suspension, when applied topically to a wound, may be effective at preventing NWS myiasis in cattle.

4. Effectiveness information in other species

There is no data demonstrating effectiveness of dicyclanil topical suspension in other species. However, it is reasonable to believe that effectiveness will be similar in target species other than sheep and cattle (i.e., goats, swine, camelids, cervids, American bison, bighorn sheep, and Sonoran pronghorn) based on the topical administration and local site of action of this drug. This drug is expected to work across different species because it appears to work through direct exposure to the parasite rather than systemic absorption in the target animal.

III. TARGET ANIMAL SAFETY

A. Foreign Margin of Safety Study in Sheep

One margin of safety study was conducted in lambs in 1996 in Switzerland using the 50 mg/mL dicyclanil topical suspension concentration. This study evaluated lambs given 1X, 3X, and 10X doses corresponding to 25 mL, 75 mL, and 250 mL, respectively, for lambs weighing between 21 and 30 kg; and 30 mL, 90 mL, and 300 mL, respectively, for lambs weighing between 31 and 50 kg. The average dose in the 10X group equated to a 461 mg/kg dose of dicyclanil topical suspension. Dicyclanil topical suspension was administered topically down the topline and around the breech on Days 1, 8, and 15. Necropsies were conducted on Days 20 and 21. Parameters measured included regular general health observations, treatment day observations, physical examinations, feed intake, wool length, body weights, clinical pathology (hematology, clinical chemistry, urine), gross necropsy, and

histopathology. There were no differences between groups for any parameter that were considered treatment related. Raw data was not available for review.

B. Field Safety Data in Sheep

Safety in sheep was additionally evaluated in multiple, large field effectiveness studies that were conducted for foreign approvals of dicyclanil topical suspension (65 mg/mL) against various blowfly species. This collection of field studies supports the in-use safety of dicyclanil topical suspension at a concentration of 65 mg/mL across numerous breeds, ages, body weights, and wool lengths of sheep across widely varying geographical locations in the United Kingdom, New Zealand, and Australia in over 10,000 animals.

C. Pharmacologic and Toxicologic Safety Information

A European Agency for the Evaluation of Medicinal Products (EMA) Dicyclanil Summary Report[2] provides further pharmacological and toxicological information on dicyclanil topical suspension. This report summarized radiolabeled pharmacokinetic studies conducted in sheep with topically applied dicyclanil topical suspension, concluding that approximately 4% of the applied dose was absorbed over a 7-day period. Toxicological studies cited in this report determined the acute LD50 (median lethal dose) by oral route in the rat was 520 mg/kg and the acute LD50 by dermal route in the rat was greater than 2000 mg/kg. This information was compared to the maximum mg/kg dose of dicyclanil topical suspension at 65 mg/mL to be given to an animal under this authorization, which is 130 mg/kg (20 mL in a 10 kg animal).

Given this information in combination with the margin of safety study in sheep demonstrating safety up to 461 mg/kg and the effectiveness studies in cattle that reported no adverse events, it is reasonable to believe that the safety profile of this drug when applied topically to a wound with local action and low systemic absorption would be similar across the target species under this EUA.

IV. HUMAN FOOD SAFETY

The human food safety assessment for the EUA of CLiK™ Extra for use in sheep, cattle, goats, swine, cervids, American bison, and bighorn sheep was based on publicly available scientific information and residue studies submitted by the sponsor, with the following as the main sources:

1. EMA/CVMP Dicyclanil Summary Report:
   European Agency for the Evaluation of Medicinal Products, Veterinary Medicines Evaluation Unit. (1999). Dicyclanil: Summary Report (1). Committee for Veterinary Medicinal Products. Document No. EMEA/MRL/573/99-FINAL-CORRIGENDUM. European Medicines Agency (EMA).

2. JECFA Monograph – Dicyclanil (INCHEM):

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[2] European Agency for the Evaluation of Medicinal Products, Veterinary Medicines Evaluation Unit. (1999). Dicyclanil: Summary Report (1). Committee for Veterinary Medicinal Products. Document No. EMEA/MRL/573/99-FINAL-CORRIGENDUM. European Medicines Agency (EMA).

Joint FAO/WHO Expert Committee on Food Additives (JECFA). (2000). Dicyclanil. In WHO Food Additives Series 45 (FAS 45-JECFA 54/75). World Health Organization, Geneva.

3. Residue depletion study report, "Dissipation of dicyclanil and its metabolite CGA 297107 in tissues of Merino sheep following application at 0 and 6 weeks offshears of dicyclanil as a pour-on" (Study No. Y96/54), submitted by the sponsor.

4. Residue depletion study report, "Safety and residue depletion of dicyclanil following topical administration of CLiKZiN® to calves" (Study No. NAH-16-034), submitted by the sponsor.

In addition, FDA utilized a residue modeling approach[3] based on the submitted residue data to account for differences between the study conditions and the conditions of use for the EUA (e.g., application site or dosing level). Based on the totality of scientific evidence, FDA concluded that food products obtained from treated animals are safe for human consumption when the conditions of use granted by the EUA are followed, including the following withdrawal period and residue warnings:

An 86-day withdrawal period is assigned to sheep, cattle, goats, swine, cervids, American bison, and bighorn sheep.

For captured cervids, captured American bison, and captured bighorn sheep, use only when there is a reasonable certainty that the treated animal will not be slaughtered or harvested for human consumption within 86 days of treatment.

Treated Sonoran pronghorn and camelids may not be used for human consumption.

A milk discard time has not been established for this product. Do not use in animals producing milk 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.

V. USER SAFETY

The product Fact Sheet contains the following information regarding safety to humans handling, administering, or exposed to CLiK™ Extra:

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

Wash hands after use.

In case of accidental ingestion, do not induce vomiting. Seek medical advice immediately and show the Fact Sheet or the label to the physician.

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[3] Greene, J. M. & Martinez, M. N. (2023). Using simulations to explore the potential effect of disease and inflammation on the frequency of violative flunixin residues in cattle. *Journal of Veterinary Pharmacology and Therapeutics,* 46(2), 91-102.

Contact with skin and eyes should be avoided. Redness and irritation may develop after skin or eye contact. Use disposable gloves and protective clothing when handling this product and wash hands after use.

In case of skin contact, remove contaminated clothing and thoroughly wash the affected parts of the body with soap and water.

In case of accidental eye exposure:

- Wash the eyes with water for at least 15 minutes.
- If wearing contact lenses, rinse the eyes first, then remove contacts and continue to rinse with water.
- If redness and swelling occur, seek medical advice immediately and show the Fact Sheet or label to the physician.

Do not eat, drink, or smoke while using this product.

Residues remain on fleece and fiber for up to three months after treatment. Wear gloves when handling treated area(s) on the animal, and do not shear treated animals during that time.

To obtain a Safety Data Sheet (SDS), contact Elanco Product & Veterinary Support at 1-800-428-4441 or visit https://www.elanco.com/us/elanco-safety-data-sheets.

VI. AGENCY CONCLUSIONS

Based on the totality of scientific evidence available to FDA, including data from foreign approvals, dose determination studies, a margin of safety study, and scientific literature, it is reasonable to believe that CLiK™ Extra, when used as authorized, may be effective for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, and that the known and potential benefits of CLiK™ Extra outweigh the known and potential risks, since NWS 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. Additionally, data demonstrate that residues in food products derived from sheep, cattle, goats, swine, cervids, American bison, and bighorn sheep treated with CLiK™ Extra will not represent a public health concern when the product is used as authorized. Sonoran pronghorn are an endangered species (32 FR 4001), therefore hunting is prohibited and a withdrawal time was not assigned. Camelids are not considered a food-producing species; therefore, a withdrawal time was not assigned.

There is no adequate, approved,[4] and available alternative to the product for prevention of NWS myiasis in sheep, cattle, goats, swine, camelids, and the following captive and

[4] "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.

captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn. There are no approved products to treat or prevent NWS in sheep, goats, swine, camelids, cervids, American bison, bighorn sheep, and Sonoran pronghorn. Although there are conditionally approved products for the prevention and treatment of NWS in cattle, CLiK™ Extra provides an important option for preventing NWS in cattle because it offers a different drug class for topical application. Cattle 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 revocation or revision 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.