

FINDING OF NO SIGNIFICANT IMPACT
for
CLINACOX™ (0.2% diclazuril) Premix
for Broiler Chickens

NADA 140-951

Mallinckrodt Veterinary, Inc.
Mundelein, IL

The Center for Veterinary Medicine has considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement will not be prepared.

Mallinckrodt Veterinary Inc., is requesting approval of new animal drug application (NADA) 140-951 for CLINACOX™ (0.2% diclazuril) Type A Medicated Article (premix). CLINACOX™ will be incorporated into the feed of broiler chickens at 1 ppm for the prevention or control of coccidiosis.

To support the approval of the application, Mallinckrodt submitted the attached environmental assessment (EA) dated May 20, 1996.

The EA contains information concerning the environmental aspects of the manufacturing of bulk diclazuril at Janssen Pharmaceutica, Beerse, Belgium and the premix at the Mallinckrodt Veterinary facility in Terre Haute, IN. Final feed will be prepared at feedmills throughout the U.S. The information indicates that the substances emitted in air, liquid and solid waste during the manufacturing are not expected to cause a significant environmental impact and that the manufacturing facilities are in compliance with applicable environmental laws and regulations.

The EA also contains extensive information concerning the environmental aspects of the disposal and use of the product and the final feed. Diclazuril has a very low water solubility and tendency to strongly sorb to soil and sediment. Data indicate that diclazuril will mineralize (biodegrade) with a half-life in the order of 1 year. The maximum expected soil concentration is 24 ppb. The maximum surface water concentration of diclazuril is expected to be 0.5 ppb. Based on these concentrations and the toxicity information contained in the EA, no adverse effects from diclazuril are expected for avian, aquatic or terrestrial species. Additionally, data in the EA support a finding that diclazuril is not expected to bioconcentrate.

The information in the EA is adequate to conclude that the manufacturing, disposal and use of CLINACOX™ for the proposed use in broiler chickens is not expected to have a significant impact on the environment.

5/1/97
Date


Director, Office of New Drug Evaluation, HFV-100

Attachment: Environmental Assessment dated May 20, 1996