FINDING OF NO SIGNIFICANT IMPACT

for

Decoquinate Medicated Feed as a Coccidiostat
in Sheep

NADA 039-417 R0046

Rhone-Poulenc Animal Nutrition N.A.
Atlanta, GA

The Center for Veterinary Medicine has carefully 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 therefore will not be prepared.

Rhone-Poulenc Animal Nutrition N.A. has requested approval of their supplemental application for the manufacture and sale of decoquinate medicated feed as a coccidiostat in sheep. Decoquinate medicated premix is approved for use in broiler chickens, cattle, and young goats for the prevention of coccidiosis as specified under 21 CFR §558.195. The finished product is manufactured by Hess & Clark, Inc., Ashland, Ohio. Bulk decoquinate is manufactured in the Rhone-Poulenc facility in Norwich, England. In support of the NADA supplement, the firm has submitted an April 23, 1993, environmental assessment (EA; attached).

We have reviewed the April 23, 1993, EA and find that it provides adequate environmental and occupational information for the site of final formulation (located at Hess & Clark, Inc., Ashland, Ohio) of decoquinate. The EA describes the substances to be emitted, controls used to limit the emissions and cites the emissions regulations at the Federal, State and local level. The EA provides a hazardous waste generator identification number, permit number for waste water discharge, and describes the methods used to assure worker safety and compliance with occupational safety and health regulations.

The April 23, 1993, EA contains a January 1, 1993, facsimile message from Rhone-Poulenc, Norwich, England to Dr. J. Fox of Rhone-Poulenc Animal Nutrition, Georgia. The facsimile message lists all materials released or potentially released to air and water from the manufacture of decoquinate at the Norwich site. It also states that the waste water is treated on site in an effluent treatment system prior to leaving the site or is disposed of by registered waste disposal contractors. A certificate of compliance from Rhone-Poulenc Norwich, England attached the EA states that the decoquinate manufacturing facility located at Norwich, England is in compliance with the waste water effluent, air pollution, and health and safety requirements of the U.K. Government. The certificate also lists the relevant sections of the U.K. Government legislation and is signed by the site manager, Rhone-Poulenc Agriculture Ltd., Norwich, England.

Additionally, an EA, contained in Public Master File (PMF) 5258, projected that the use of decoquinate in sheep should have no detrimental effects upon the environment. Information provided in the PMF EA indicates that decoquinate will enter the environment via sheep manure used as fertilizer on agricultural soils. Although, decoquinate may be stable against microbial degradation, its use in sheep is not expected to contribute significantly to the concentration of decoquinate in the environment. The EA indicates that the low levels of decoquinate expected in the soil should have no impact on the environment from its use in

sheep. Because of decoquinate soil adsorption, little movement into surface or ground water is expected.

The information provided in the April 23, 1993, EA for the manufacture of the product and the EA in PMF 5258 is adequate for us to determine that the manufacture and use of the product in sheep is not expected to have a significant impact on the human environment.

2/15/94
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Attachments: Environmental Assessment dated April 23, 1993, and September 1989