

FINDING OF NO SIGNIFICANT IMPACT

for

IVOMECC[®] Premix for Swine

SEP 23 1993

NADA 140-974

Merck & Co., Inc.
Rahway, NJ

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.

Merck & Co. has requested approval of NADA 140-974 for the use of ivermectin for the treatment and control of endo- and ectoparasites in swine through medicated feed. The recommended dose is 2 ppm or approximately 100 µg/kg body weight per day for seven consecutive days. Approximately one-fourth of the swine population in the United States is treated with the injectable formulation of ivermectin. Additional use of the premix formulation in feed is estimated to extend total use of ivermectin to approximately one-third of the swine population.

In support of the NADA, Merck & Co. has submitted a certified environmental assessment (EA, dated July 15, 1991; copy attached) under 21 CFR 25.31a(a) as required for animal drugs. The EA includes information concerning the introduction of substances into the environment for the site of production of the active ingredient and finished product in Danville, PA; Barceloneta, PR; and Haarlem, Holland. The EA cites applicable environmental laws and regulations and states that all facilities are in compliance with the environmental control regulations. Fate and effects data are used in the EA to develop a hazard assessment for terrestrial and aquatic ecosystems.

Appendix B of the EA provides Material Safety Data Sheets (MSDSs) for Avermectin in Broth; Avermectin Spent Broth, Detoxified; Avermectin Pure; Ivermectin; and IVOMECC[®] Type A Medicated Article (Premix). The firm states that plant personnel have MSDSs available for review and that manufacturing is in compliance with applicable occupational safety acts and regulations.

The proposed use of IVOMECC[®] Premix for the treatment and control of endo- and ectoparasites in swine would not be expected to cause significant environmental impacts. Submitted data show that projected ivermectin concentrations in the environment are below demonstrated effect levels in various species and that degradation of these levels would be expected.

1/27/92
Date

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1-27-92
Date

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1/27/92
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Attachment: Environmental Assessment, dated July 15, 1991.