FINDING OF NO SIGNIFICANT IMPACT

for

Synanthic (oxfendazole)
9.06% and 22.5% Suspension
for Cattle

NADA 140-854

SYNTEX (U.S.A.) Inc.
Palo Alto, CA

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.

SYNTEX is requesting approval of the use of Synanthic (oxfendazole) 9.06% and 22.5% suspension for cattle. Synanthic is to be used in cattle as a broad-spectrum anthelmintic. The product will be administered as a single dose (4.5 mg/kg body weight) with retreatment at four to six weeks if reinfection with helminths is a common occurrence.

In support of the new animal drug application, SYNTEX has conducted a number of studies to determine the potential environmental fate and effects of oxfendazole and summarized the results of these studies in the attached environmental assessment (EA).

Information in the EA and the attached April 30, 1990, letters from Diamond Scientific Company and Cooper Animal Health, Inc., indicate that the manufacture of the bulk drug product at SYNTEX's facilities in Grand Bahama Island, Bahamas and Boulder, Colorado and the finished product at Diamond Scientific and Coppers Animal Health are in compliance with the applicable Federal, state and local regulations, including the occupational regulations. Therefore, the manufacture of the product is not expected to have a significant impact on the environment.

Information in the EA also indicates that residues of oxfendazole are expected to be introduced into the environment as a result of the use of the product. These residues are expected to be moderately bound by soil and particulate matter so that concentrations in runoff from feedlots and soils are expected to be low and are not expected to have significant impacts on aquatic species. Data also indicate that residues that enter aquatic systems are expected to degrade upon exposure to sunlight. Tables of the quantum yields (QcE) and seasonal (spring, summer, fall and winter) half-lives for the photodegradation of oxfendazole and its hydrolytic product are attached (Tables 1 & 2).

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Analysis of the data from two definitive plant studies (No Observed Effect Concentrations for reductions in observed parameters) and an earthworm toxicity study indicate that residues of oxfendazole in agricultural soil are not expected to have adverse impacts on plants or soil invertebrates. Tables of the observed seedling growth effects (reductions in Table 1a; increases in Table 1b) on shoot length, shoot weight and root weight of cucumber, pinto bean, rye, corn, wheat, and soybean (2 studies) as calculated by the Center for Veterinary Medicine, Biometric Branch, are attached. It is also important to note (Tables 2a and 2b, that the solvent used in the plant studies, in some cases, significantly influenced plant growth and, therefore, both the reductions and the increases observed may have been magnified by the solvent. Although some accumulation of oxfendazole may occur, oxfendazole residues that are present in soil are expected to degrade from hydrolysis and, upon exposure to sunlight during soil turnover, from photolysis. No exposures of terrestrial vertabrates species are expected.

5/1/90
Date

Preparer,
Environmental Sciences Staff, HFV-162

5/1/90
Date

Primary Action Officer, HFV-135

5/1/90
Date

Chief,
Environmental Sciences Staff, HFV-162

Attachments