

FINDING OF NO SIGNIFICANT IMPACT

for

Laidlomycin Propionate Potassium (Cattlyst™) in Feedlot Cattle

NADA 141-025

Syntex Animal Health
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 Animal Health has requested the use of laidlomycin propionate potassium (Cattlyst™) for use in feedlot cattle for improved average daily weight gain and feed efficiency. Cattlyst™ is a feed premix that contains 11 % (50 g/lb) laidlomycin propionate potassium as active ingredient, and is to be incorporated in cattle rations at 0.10 lb/ton.

The firm has submitted the attached environmental assessment (EA) dated July 1993 that addresses the environmental and occupational exposure concerns for the manufacture and use of this new animal drug substance. The EA appendices (Appendix A-V) contain: 1) a listing of the applicable laws and regulations and statements of compliance with these requirements, 2) Material Safety Data Sheets (MSDSs) for laidlomycin sodium, laidlomycin propionate potassium, and laidlomycin propionate potassium premix 11 %, and 3) supporting study summaries that are referenced in the EA. The summaries accurately describe the results of confidential full study reports.

The EA describes the sites of product manufacture (Syntex Agribusiness, Inc., Springfield, MO and Glatt Air Techniques, Inc., Ramsey, NJ) and the environments at those sites. The firm describes and provides evidence of compliance with the applicable laws and regulations regarding the treatment and discharge of air and wastewater emissions at both manufacturing sites. In addition to the MSDSs, the EA describes procedures to prevent occupational exposures at the manufacturing sites and at the site of mixing with feed.

The EA describes the expected introductions of laidlomycin into the environment through excreta from treated cattle. The firm demonstrates that 1.66 mg/kg of laidlomycin sodium and 0.443 mg/kg C-3 despropionyl laidlomycin sodium (major metabolites) can be expected to be excreted per head per day.

Syntex conducted a series of physical/chemical studies with laidlomycin to determine the fate of the amount of the compound that entered the environment. The studies included the determination of the: 1) acid dissociation constant, 2) water solubility, 3) n-octanol/water partition coefficient, 4) vapor pressure, 5) soil adsorption/desorption constants, 6) hydrolysis, and 7) biodegradation. The biodegradation study showed that laidlomycin propionate degrades rapidly to laidlomycin sodium, C-3 despropionyl laidlomycin sodium and several polar metabolites.

Using these fate studies, the firm determined expected maximum concentrations of laidlomycin in feedlots and in manure-treated soils. The firm calculated that 3.76 mg/kg and 3.22 mg/kg of laidlomycin sodium and C-3 despropionyl laidlomycin sodium, respectively, could be expected to be found in aged feedlot waste. In soils receiving those wastes, 0.0752 mg/kg and 0.0644 mg/kg could be expected.

Syntex also conducted a series of acute toxicity studies to determine what effects laidlomycin might have on representative populations of organisms in the environment. The studies included: 1) mammalian toxicity studies in mice rats and dogs, 2) acute toxicity of laidlomycin sodium to *Daphnia magna*, 3) acute toxicity of laidlomycin sodium to *Hyalella azteca*, 4) acute toxicity of laidlomycin sodium to bluegill sunfish and rainbow trout, 6) the determination of effects of laidlomycin sodium on seed germination and root elongation, and 7) the determination of effects of laidlomycin sodium on seedling growth in sand and natural field soils. These studies showed that the expected concentrations of laidlomycin in the aquatic and terrestrial environment are not expected to have significant impacts on populations that may potentially be exposed.

We have reviewed the EA and the supporting documentation and find that together they provide adequate information to conclude that the approval of NADA 141-025 is not expected to have a significant effect on the quality of the human environment.

11/30/93

Date

Roger A. Jones

Preparer, Environmental Sciences Staff, HFV-152

11/30/93

Date

Daniel A. Benz

Primary Action Officer, HFV-126

11/30/93

Date

Charles E. Eubank

Chief, Environmental Sciences Staff, HFV-152

Attachment: Environmental Assessment dated July 1993