FINDING OF NO SIGNIFICANT IMPACT
for
Rumensin® (monensin) Type A
Medicated Article for Dairy Cattle

Elanco Animal Health
Indianapolis, IN

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.

Elanco Animal Health is requesting approval of a supplemental new animal drug application (NADA) for Rumensin® (monensin) Type A Medicated Article. The supplement provides for the use of monensin at up to 473 mg/head/day to be fed continuously. To support the approval of the supplement, Elanco has provided the attached environmental assessment (EA) dated July 1997.

At the proposed use level of 473 mg/head/day, the concentration of monensin estimated in dairy cattle feces is 3 ppm. The subsequent concentration in soil after incorporation at approximately 15 ton (dry weight) per acre is 0.09 ppm. Subsequent runoff may contain 0.5 ppb monensin. The runoff concentration differs from the 0.4 ppm estimated in the EA but the 0.4 ppm concentration is unrealistic. It does not account for degradation, solubility, sorption or other factors that impact on the movement of chemicals to runoff water. The 0.5 ppb concentration was derived from the Generic Expected Environmental Concentration Program developed by the Environmental Protection Agency, Office of Pesticides Program. A printout of the result of the program is attached.

At these expected environmental concentrations, the data provided in the EA indicate that adverse effects are not expected on soil (plants, birds, earthworms and microbes) or aquatic species (Bluegill, rainbow trout and daphnia). The phytotoxicity data are relatively weak and present uncertainty. There is a lack of adequate microbial data which increases uncertainty about affects on microbial mediated nutrient cycling within manure. There is also the potential for adverse effects on dung dwelling insects and birds. In both cases, the effects would be anticipated to be acute and of short duration. Data indicate that monensin is expected to be metabolized rapidly and degrade at a relatively rapid rate..

Additionally, monensin is already approved (21 CFR 558.355) for use in beef cattle in confinement and on pasture. The maximum concentration of the product introduced into the environmental from this approval is not expected to be significantly higher than the maximum already being introduced into the environmental from approved uses. There have been no reports of adverse environmental effects resulting from the use of monensin.

The information in the EA is adequate to conclude that the use of monensin up to 473 mg/head/day is not expected to have a significant impact on the environment. Any other supplements submitted for the use of monensin at this level or below would not be expected to change the environmental introductions or impacts of monensin.

11-26-97
Date

Robert C. Livingston
Director, Office of New Drug Evaluation, HFV-100

Attachment: GENEEC Table
July 1997 Environmental Assessment

Generic Expected Environmental Concentration Program (GENEEC)
Environmental Protection Agency, Office of Pesticides Program

RUN No. 1 For Rumensin® (monensin) at 473 mg/head/day

INPUT VALUES

RATE (#/ACRE) ONE(MULT)	APPLICATIONS NO.-INTERVAL	SOIL KOC	SOLUBILITY (PPM)	% SPRAY DRIFT	INCORP DEPTH(IN)
0.165 (0.165)	1 - 1	547.0	63.0	0	6.0

FIELD AND STANDARD POND HALF-LIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)
7.50	0	N/A	43.90	0

GENERIC EXPECTED ENVIRONMENTAL CONCENTRATIONS (PPT)

PEAK GEEC	AVERAGE 4 DAY GEEC	AVERAGE 21 DAY GEEC	AVERAGE 56 DAY GEEC
523.27	515.07	475.37	419.94