

ENVIRONMENTAL ASSESSMENT FOR THE USE OF
RUMENSIN® PREMIXES IN THE FEED OF GOATS

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A Division of Eli Lilly and Company
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Indianapolis, Indiana 46285

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ENVIRONMENTAL ASSESSMENT FOR THE USE OF
RUMENSIN® PREMIXES IN THE FEED OF GOATS

1. DATE June 1987
2. APPLICANT Elanco Products Company
A Division of Eli Lilly and Company
3. ADDRESS Lilly Corporate Center
Indianapolis, Indiana 46285
4. DESCRIPTION OF THE PROPOSED ACTION

A Supplemental New Animal Drug Approval has been requested for use of RUMENSIN® Premixes in the feed of goats. Monensin sodium is the active ingredient in the RUMENSIN Premixes. It is proposed that monensin be fed to goats at 20 g monensin/ton of complete feed (22 ppm) for the prevention of coccidiosis and to reduce oocysts acquired from normal infection. Some of the species to be controlled are Eimeria crandallis, E. christenseni and E. ninakohlyakimovae. Prevention of coccidiosis in goats is especially important since goats subjected to stressful conditions such as crowding and somewhat unsanitary conditions or weaning and shearing are very susceptible to infection. Outbreaks are characterized by diarrhea, weight loss, unthriftiness and increases in mortality. Approval of the use of RUMENSIN Premixes in the feed of goats would result in a small increase in the total amount of monensin sodium sold in the United States.

RUMENSIN® (monensin sodium, Elanco)

RUMENSIN Premixes are already approved for use in the rations of cattle (up to 360 mg monensin/head/day) fed in confinement for slaughter (21CFR 558.355; December 16, 1975). RUMENSIN Premixes are also approved (21CFR558.355; Federal Register, July 28, 1978) for use in the rations of growing cattle in pastures (up to 200 mg monensin/head/day). In 1983 approval for use of RUMENSIN Premixes in pastured cattle was expanded to include beef and dairy replacement heifers. An Environmental Impact Analysis Report (1) has been provided for RUMENSIN Premixes fed to cattle. An Environmental Assessment for the use of RUMENSIN Premixes in the feed of reproducing beef cattle (2) was submitted in 1986 to support the request for approval of NADA 95-735. The current Environmental Assessment is abbreviated since it addresses the use of RUMENSIN Premixes to prevent disease in goats, a minor species (21CFR514.1[d]).

Approval of the proposed action would authorize the use of RUMENSIN Premixes to be expanded to include goats maintained in confinement. Approval of the proposed action would also authorize the fermentation and processing plants of Eli Lilly and Company at Clinton and Lafayette, Indiana to manufacture and package the RUMENSIN Premixes to be sold in the United States for use in the rations of goats.

Based on the proposed action, monensin could potentially be introduced into the following environments:

- a) The environment adjacent to the manufacturing plants.
- b) The environment adjacent to facilities which mix RUMENSIN with feed.
- c) Confinement lots where residues may be found in goat excreta.
- d) Agricultural lands where waste products from goats may be used as fertilizer.

- e) Aquatic systems where runoff may flow from sites receiving waste products of goats.

5. IDENTIFICATION OF CHEMICAL SUBSTANCE

A. RUMENSIN PREMIXES

RUMENSIN Premixes will be incorporated into rations of goats maintained in confinement. Monensin sodium is the active ingredient in the RUMENSIN Premixes and is produced in dried mycelial biomass and crystalline forms. The raw material is added to the premixes to achieve monensin concentrations of 20, 30, 45, and 60 g/lb. RUMENSIN Premixes may contain diluents such as rice hulls.

B. MYCELIAL MONENSIN

Monensin is produced by the fermentation of a strain of Streptomyces cinnamomensis, an organism isolated from soil (3). The most economical procedure to prepare a usable form of monensin is to harvest the fermentation culture in such a way as to combine monensin with the mycelial cells of the producing organisms and the unused components of the feedstock used in the fermentation to achieve growth of the organism. Thus, the dried mycelial or biomass form of monensin may contain nutrients which can commonly be found in goat feedstuff.

C. MONENSIN (References 3 and 4)

Monensin consists primarily of monensin factor A, but small amounts of monensin factor B and very small amounts of factors C and D do occur. Monensin factor A accounts for at least 90 percent of the

microbiologically active material of mycelial monensin. The characteristics of monensin factor A are discussed in this section. Monensin is a monocarboxylic polyether compound which complexes with monovalent alkali cations and shows ionophorous activity with a selectivity of $\text{Na}^+ > \text{K}^+ > \text{Rb}^+ > \text{Li}^+ > \text{Cs}^+$.

Monensin Sodium:

During the manufacturing process, monensin is exposed to sodium ions during a pH adjustment giving rise to monensin sodium which is the chemical form in the product.

Chemical Name (acid form):

Stereoisomer of 2-[2-ethyloctahydro-3'-methyl-5'-tetrahydro-6-hydroxy-6-(hydroxymethyl)-3,5-dimethyl-2H-pyran-2-yl][2,2'-bifuran]-5-yl]-9-hydroxy- β -methoxy- $\alpha, \gamma, 2, 8$ -tetramethyl-1,6-dioxaspiro[4,5]decane-7-butanoic acid.

CAS Registry Number:

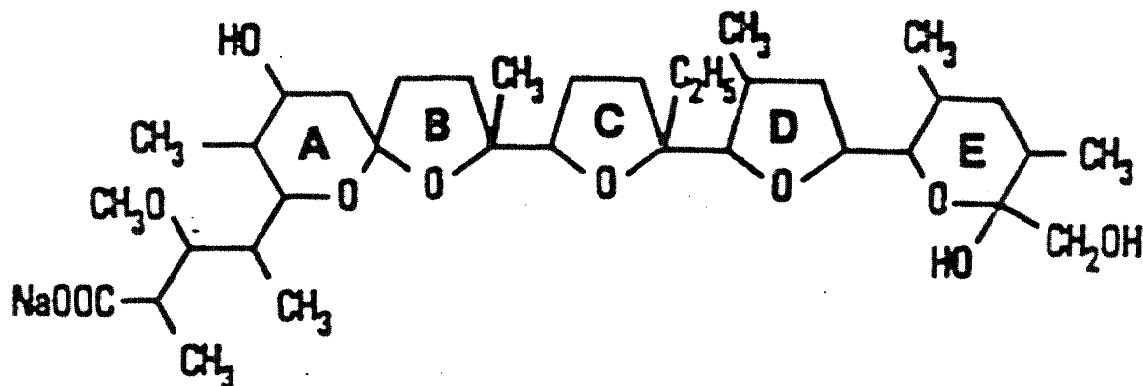
17090-79-8

Molecular Formula:

$\text{C}_{36}\text{H}_{62}\text{O}_{11}$ (acid),
 $\text{C}_{36}\text{H}_{61}\text{O}_{11}\text{Na}$ (salt)

Molecular Weight:

670 (acid), 692 (sodium salt)

Structural Formula:Solubility

water

pH 7 63 mg/L
pH 9 0.85 mg/L

ethyl acetate

very soluble

chloroform

very soluble

acetone

very soluble

benzene

very soluble

methanol

very soluble

hexane

slightly soluble

Melting Point: 103-105°C (acid)
267-269°C (sodium salt)UV absorption: NonepKa value: 6.65 (66% DMF)Specific Rotation: + 47.7° (acid), + 57.3° (sodium salt)Vapor pressure: Non-volatile solid based on molecular weight, melting point, and thermogravimetric analysis.

6. INTRODUCTION OF SUBSTANCE INTO THE ENVIRONMENT

A. INTRODUCTION OF SUBSTANCES FROM THE MANUFACTURING SITE

The manufacturing process for monensin, in conjunction with the corresponding pollution control practices at each of the plant sites, is designed to have minimal environmental impact. These plant sites are located near Clinton and Lafayette, Indiana. Monensin is produced by a fermentation process and is recovered by processes utilizing unit operations such as evaporation, centrifugation or filtration, drying, pelletizing, granulation by crushing, screening and blending.

Essentially no monensin will be released from the manufacturing process. The only releases of monensin from manufacturing operations will be in dilute washwaters used to rinse the empty fermentation and processing facilities. At these plant sites, these washwaters would be treated by wastewater concentration and pyrolysis, by land application or by microbiological degradation.

Residual biodegradable fermentation nutrients from the manufacture of other fermentation products at each of the plant sites are discharged to receiving rivers at rates significantly below permitted limitations. Since monensin will not be the only fermentation-based product manufactured at these plant sites, it will account for a small portion of the permitted discharge of residual nutrients expressed as biological oxygen demand (BOD).

Essentially no other wastewater pollutants or liquid, solid or gaseous pollutants from the manufacture of monensin will be allowed to enter the environment. Therefore, the manufacture of monensin will have a minimal effect on the environment at these plant sites.

Limitations for atmospheric pollutant emissions and wastewater pollutant discharges, and disposal practices for other liquid and solid wastes applicable to these plant sites, are defined by regulations administered, in certain instances, by the U.S. Environmental Protection Agency and, in certain other instances, by Indiana's Department of Environmental Management (IDEM).

The following operating permits for those manufacturing emission sources and control facilities which would produce monensin at these plants currently are administered by IDEM's Office of Air Management.

<u>Location</u>	<u>Permit Identification No.</u>	<u>Issued</u>	<u>Expiration</u>
Clinton	83-09-87-0067	Issuance pending*	
Clinton	83-09-87-0068	Issuance pending*	
Clinton	83-09-87-0073	Issuance pending*	
Lafayette	79-04-90-0372	Oct. 09, 1986	Apr. 01, 1990
Lafayette	79-04-90-0386	Oct. 09, 1986	Apr. 01, 1990

*(This permit is being extended administratively by IDEM until it issues the renewal permit, for which a timely application has been submitted by Eli Lilly and Company.)

The following NPDES permits for the discharge of wastewaters from these plants to the Wabash River currently are administered by IDEM's Office of Water Management.

<u>Location</u>	<u>NPDES Permit No.</u>	<u>Issued</u>	<u>Expiration</u>
Clinton	IN 0002852	Sep. 23, 1985	Aug. 31, 1990
Lafayette	IN 0002861	Sep. 30, 1987	Sep. 30, 1992

No hazardous wastes and essentially no solid wastes will be generated in these manufacturing operations. Processes which use organic solvents provide for recovery and reuse of solvents, and those operations where solvents are present are served by condensers, carbon adsorbers or scrubbers to prevent solvent emissions from being discharged to the atmosphere. Those manufacturing operations which use dry procedures are

served by dust control facilities to prevent particulate matter emissions from being discharged to the atmosphere. Packaging materials, non-recyclable tailings and floor sweepings from these plants either are incinerated at the Clinton plant with industrial and domestic trash from other sources or are landfilled.

Based on the information above, any atmospheric emissions, wastewater pollutant discharges and disposal practices for other wastes from the manufacturing processes for monensin will comply with appropriate statutes, regulations, and permits.

B. INTRODUCTION OF SUBSTANCE FROM FEED MIXING LOCATIONS

Commercial feed mills will be a major site of feed mixing. These feed mills have to meet Good Manufacturing Practice Standards for feeds. With the required manufacturing controls for feed, inventory accountability, and quality assurance procedures, the potential for release of monensin sodium into the environment at these locations should be minimal.

C. INTRODUCTION OF SUBSTANCE AT THE USE SITE

Texas A&M University estimates indicate that there are about 2.5 million goats in the United States each year. The goat industry is centered in the states of Texas, Oklahoma, California and New Mexico. Direct marketing of RUMENSIN Premixes to major commercial feed mills will help to minimize environmental exposure during the product distribution process.

RUMENSIN would be used in the rations of goats maintained in confinement. The only feeding level recommended is 22 mg/kg total diet

and will be fed continuously to each goat. Feed consumed by a 35 kg goat is approximately 1.4 kg/day. If all 2.5 million goats were fed a RUMENSIN Premix daily for up to one year, the maximum amount of monensin sodium that could be used annually would be 28,290 kg (31 mg/head/day x 365 days x 2.5×10^6 goats). Only 10% of the 2.5 million goats are expected to receive monensin in their diet. Therefore, it is estimated that goats will actually be fed about 2,829 kg monensin sodium in their diets each year. This is less than 1% of the monensin sodium already sold in the United States.

For additional information pertaining to the fate of monensin in the environment, please refer to Public Master File 5055.

12. LIST OF PREPARERS

The following Lilly personnel are responsible for the preparation of this Environmental Assessment:

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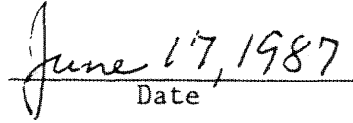
Michael J. McGowan
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13. CERTIFICATION

The undersigned official certifies that the information presented in the Environmental Assessment is true, accurate, and complete to the best of his knowledge.



Merle E. Amundson, Ph.D.
Executive Director
Toxicology Division
Lilly Research Laboratories


Date

14. REFERENCES

1. Elanco Products Company. 1975. Environmental impact analysis report for use of monensin in the feed of beef cattle. NADA 95-735.
2. Elanco Products Company. 1986. Environmental assessment for the use of RUMENSIN Premixes in the feed of reproducing beef cattle. NADA 95-735.
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ENVIRONMENTAL IMPACT ASSESSMENT FOR THE USE OF
MONENSIN TO CONTROL COCCIDIOSIS IN GOATS

JULY 31, 1986

I. Description of Use

It is proposed that monensin be fed at 22/mg/kg total diet in order to prevent coccidiosis in goats and to reduce oocysts acquired from normal infection. Some of the species to be controlled are Eimeria crandallis, E. christenseni and E. ninakohlyakimovae. Prevention of coccidiosis in goats is especially important since goats subjected to crowded and somewhat unsanitary conditions as well as other stressful conditions resulting from weaning and shearing are very susceptible to infection. Outbreaks are characterized by diarrhea, weight loss, unthriftiness and increases in mortality.

II. Chemical Identity and Properties

Monensin is produced by Streptomyces cinnamomensis and has the molecular formula $C_{36} H_{62} O_{11}$, a molecular weight of 670.90 and the chemical name 2-[5-ethyltetrahydro-5-tetrahydro-3-methyl-5-[tetrahydro-6-hydroxy-6-(hydroxymethyl)-3,5-dimethyl-2H-pyran-2-yl]-2-fungl]-2-fungl]-9-hydroxy-B-methoxy-, ,2,8-tetramethyl-1,6-dioxaspiro[4,5]decane-7-butyric acid. The monohydrate, molecular weight 688.90 has a melting point of 103-105°C. During the purification, the sodium salt is produced by pH adjustment. The sodium salt $C_{36} H_{61} O_{11} Na$ has a molecular weight of 692. It has a melting point of 267-269°C is slightly soluble in water and more soluble in hydrocarbons and very soluble in many organic solvents.

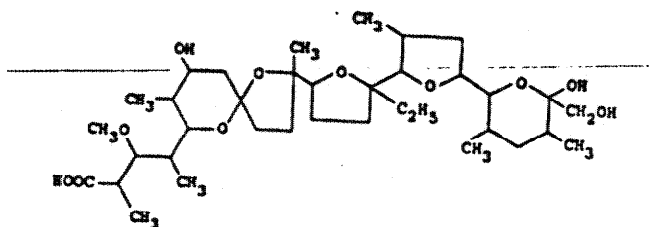
Monensin monohydrate: $[\alpha]_D^{25} + 47.7^\circ$, pK_a 6.6 in 66%

Dimethylformamide

Monensin sodium salt: $[\alpha]_D^{25} + 57.3^\circ$ methanol

Monensin exhibits no UV absorption. The molecular formula was determined by mass spectrometry. The structure of monensin was established by x-ray crystallographic analysis.

Monensin and its sodium salt is very stable under alkaline conditions structure of monensin.



A. Introduction into the Environment

I. Manufacturing

After fermentation, monensin activity is recovered by drying the mycelial solids. The dried mycelia are mixed with other ingredients to make the premixes used in animal agriculture. The raw materials used include: carbon sources such as mono and polysaccharides and vegetable and animal oils; nitrogen sources include protein products of vegetable and animal origin and inorganic nitrates or ammonium salts; additional nutrients and buffering salts include calcium carbonate, manganese chloride and iron sulfate. Materials used in the recovery operation include sodium hydroxide, amyl alcohol and small amounts of silicone and/or polyglycol antifoaming agents. All solid and liquid raw materials are stored in appropriate bins, tanks and closed warehouses. Use areas are defined for easy removal and disposal of materials in the event of spillage.

A suitable warning statement should be incorporated in label instructions for monensin premixes such as: Warning: When mixing or handling [product name] premix, use protective clothing, impervious gloves and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water.

II. Waste Treatment

Waste water - Waste water from the fermentations and recovery process are evaporated and the resulting solids are burned. Process effluent water from the processes are added to the final plant effluent which is monitored continually. Effluent standards are set by the EPA (Permit No. IN 0002852) and the State Of Indiana.

Solvent Recovery - Amyl alcohol used to extract the mycelia and fermentation liquor are recovered in a solvent recovery operation and recycled for residue. Effluent from the solvent recovery operation join the final effluent which is monitored continuously.

Fermentation Filter Cake - Little if any fermentation solids are generated as waste since the vast majority of solids are used for the premix material. Any solid waste is burned in an approved incinerator. (State of Indiana Permit No. 83-11-9-0007).

Air Emissions - Air emissions come from fermentor vents, diesel engines and steam generation units. Emissions from gas and fuel oil combustion meet standards. Oils and solids collected from fermentation waste water streams are incinerated in an approved waste solids boiler used to generate steam for processing. (State of Indiana Permit No. 83-11-9-0010).

Solid Wastes - Trash, containers, papers and other combustible solid wastes are incinerated. The ash produced is disposed in on-site landfills. (Indiana Permit No. 83-11-9-0007).

B. Introduction Through Proposed Use in Goats

The use of monensin in goats for the prevention of coccidiosis is necessary to prevent significant economic losses. Goats are especially susceptible to infection in crowded conditions and the stresses so associated as well as the stresses resulting from shearing and weaning. The feeding level recommended is 22 mg monensin/kg total diet, to be fed continuously.

The size of the animals used in these assumptions were based upon the size of the animals used in the efficacy studies. The following assumptions were used to calculate the worst case situation:

- 1- Weight of goats to be fed: 35 kg.
- 2- Feed consumed/day 1 goat: 3.0 lb.
- 3- Weight of waste produced/day/goat: 1/5 lbs.
- 4- Excretion of active monensin is 45% of the monensin fed
- 5- The feeding of monensin occurs continuously.
- 6- Manure was collected biweekly, held and disposed of by plowing in at the rate of 20 tons/acre.
- 7- A 5000 goat model was utilized - considerably more goats than found in normal practice.
- 8- A dairy goat housing model was used to estimate feeding levels.
- 9- Disposal rates were based on excretion and included a modest contribution of bedding (3 lbs bedding/goat) to minimize dilution.
- 10- No degradation of the monensin excreted occurred prior to soil disposal.

In addition, for these calculations, it is assumed that the housing will be cleaned regularly; and for the purposes of the worst-case situation every two weeks.

Calculation of Manure Production:

$$\frac{5000 \text{ goats} \times 1.5 \text{ lbs manure/day} \times 14 \text{ days}}{2000 \text{ lbs/ton}} = 52.50 \text{ tons manure/two weeks}$$

Added to this is the 3 lbs. of bedding/goat there will be a total of 15,000 lbs. or 7.5 tons of bedding that must be plowed into the soil.

Calculation of Monensin Levels in Waste

14 days x 5000 goats x 0.45 (metabolism) x 3.0 lbs. feed/goat/day
x 22.0 mg monensin/kg x 0.454 kg/lb =
943,866 mg monensin excreted/two weeks

$$\frac{943,866 \text{ mg} \times 1000 \text{ ugs/mg}}{60 \text{ tons waste} \times 2000 \text{ lbs} \times 454 \text{g/lb}} = \frac{943,866}{54,480} = 17.3 \text{ ugs monensin/g waste}$$

Calculation of Monensin Concentration in Soil after plow-in

$$\frac{943,866,000 \text{ ugs monensin in waste (14 days)}}{60 \text{ tons waste} \times 43,560 \text{ ft}^2/\text{acre} \times 144 \text{ in}^2/\text{ft}^2 \times 6" \text{ plow-in depth} \times 16.4 \text{ cm}^3/\text{in}^3 \times 1.5 \text{ g/cm}^3}$$

$$\frac{9.44 \times 10^8 \text{ ug monensin}}{2.78 \times 10^9 \text{ g soil}} = 0.34 \text{ ug monensin/g soil}$$

Degradation in the Soil

The following data submitted as a part of the EIAR for monensin use in chickens and cattle [NADA 38-878 and NADA 95-735] indicated that monensin degraded in soil with a reasonable degree of rapidity. The actual half-life of monensin degradation in soil was difficult to calculate, accurately, from available data since there was no identification of the moiety being degraded. Also, degradation occurred in a stepwise fashion. These data, although somewhat general, did indicate that the monensin molecule was readily degradable with a half-life approximating 5-7 weeks.

Decline of ¹⁴C Monensin in Soil

Time Weeks	Radioactivity	
	dpm/g soil	% initial activity
0	800	100
2	635	79
5	413	52
9	249	31
15	247	31
23	187	23
29	188	23

In a second study by Donoho, (1984) monensin degraded in the soil, whether mixed only with soil or mixed with a soil-feces combination rather easily. The half-life approximated 3 to 4 weeks. The degradations of monensin in soil alone or in a combination of soil and feces were essentially identical indicating that normal microbial soil populations were capable of degrading the monensin molecule.

Loss of Monensin in Soil
Monensin Conc ppm

Days	Soil Alone	Soil + Manure
0	1.08	1.04
5	1.08	1.01
12	0.86	0.80
20	Trace	Trace
26	Trace	Trace
33	Trace	None

In spite of the discrepancy between half-life estimations, monensin does degrade in the soil with a fair degree of rapidity and hence should not accumulate in the soil.

Potential for Leach

From the data presented in NADA 95-735, there is little definitive data concerning potential leach. There is the claim that "monensin tends to become bound in the soil". Since monensin is insoluble in water and lipophilic, there will be only a modest tendency for aqueous-mediated transport. Leach studies reported in the 1978 Draft Environmental Impact Statement indicated a loss of 5% from soil columns.

The fact that the southwest, where the large majority of the goat population would be grown and maintained, has relatively low annual rainfall (on the average) itself does not indicate leach would not be a factor. The Southwest area, especially Texas, has been subjected to extremes in rainfall which can result in considerable soil erosion. However, the levels of monensin from such a phenomenon would also be low. Assuming all the monensin plowed in from one disposal is dispersed into a 6" rain fall, the concentration in the 6" volume of water would be

$$\frac{943,866 \text{ mg monensin} \times 1000 \text{ ug/mg}}{3 \text{ acres} \times 43,560 \text{ ft}^2 \times 144 \text{ in}^2/\text{ft}^2 \times 6" \text{ water} \times 16.4 \text{ cm}^3/\text{in}^3} = 1.979 \times 10^8 \text{ ML}$$

$$4.77 \text{ ugs monensin/cm}^3 \text{ water} = 4.77 \text{ ugs monensin/ml (1cm}^3=1\text{ml)}$$

Since flood conditions would cause a dilution many thousands times the maximum calculated value, any suspended monensin should be in the ppb or ppt concentration range, levels incapable of any biological impact.

Bioaccumulation

Monensin is soluble in organic solvents and virtually insoluble in water indicating lipophilic tendencies. Octanol partition data were not available to make estimates of bioaccumulation. Both metabolic studies and soil degradation data indicated that there is only a modest potential for bioaccumulation. If such a phenomenon would occur, it would be transitory at best.

Effects on Microorganisms

There are no definitive data showing that monensin mediates the development of resistance, plasmid or chromosomal, in microorganisms. The two and four-fold increases in resistance noted in the anaerobes Clostridium perfringens and Bacteroids fragilis, after many passages or exposures (40) to monensin indicate more of selection for a slightly more resistant sub-population of the test strains than any mutation.

Monensin levels of 25 ppm had no deleterious effects on the microbial degradation of feed lot waste (1978 Draft Environmental Impact Statment). This observation occurred regardless of the fact that the in vitro MIC's of monensin to many organisms is below the 25 ppm level. Thus it is expected that potential soil disposal would cause no effects on the microbial population. The calculated level of 0.34 monensin/g soil was below the agar dilution MIC. Solution MIC values usually are approximately 1/4 of the agar dilution MIC values.

Antimicrobial Spectrum of Monensin in vitro^a

<u>Organisms</u>	<u>MIC of monensin (ug/ml=ppm)</u>		
	<u>At 24 hr</u>	<u>At 48 hr</u>	<u>At 72 hr</u>
<u>Bacteria</u>			
<u>Staphylococcus aureus</u> 3055	0.78	0.78	
<u>Bacillus subtilis</u> ATCC 6633	1.56	1.56	
<u>Mycobacterium avium</u> ATCC 7992	—	0.78	
<u>Streptococcus faecalis</u>	3.13	12.5	
<u>Lactobacillus casei</u> ATCC 7469	0.78	0.78	
<u>Leuconostoc citrovorum</u> ATCC 8081	0.78	3.13	
<u>Proteus vulgaris</u> sp.	50.0	100.0	
<u>Vibrio metschnikovii</u>	50.0	50.0	
<u>Fungi</u>			
<u>Alternaria solani</u>			6.25
<u>Botrytis cinerea</u>			3.13
<u>Helminthosporium sativum</u>			50.0
<u>Pullularia</u> sp.			1.56
<u>Penicillium expansum</u>			12.5
<u>Sclerotinia fructicola</u>			3.13

^aAgar dilution test method.

(EIAR, Elanco, 3/26/75 NADA 95-735)

At worst, the calculated soil levels would be close to the expected solution MIC for a few species. Degradation of monensin in the soil would bring the concentrations well-below any potentially inhabiting levels within a relatively short period of time, probably within 3 weeks.

Effects on Representative Non-Target Organisms

The LD₅₀'s, EC₅₀'s and NOEC values for non-target species are listed in the following summary. These values are considerably above the calculated soil disposal level and any possible leach or erosion levels. Hence, the presence of monensin at the calculated levels should not cause any anticipated effects on non-target species.

Effects of Monensin on Some Non-Target Organisms

Organisms	Monensin Concentration		Sodium Salt
	LD ₅₀ mg/kg	LC ₅₀ mg/L	EC ₅₀ NOEC mg/kg or mg/L
Bluegill (<u>Lepomis macrochirus</u>) ^(a)		16.6	3.1
Rainbow Trout (<u>Salmo gairdneri</u>) ^b		9.0	0.70
Daphna magna ^(c)			10.7 4.2
Earthworms (<u>Lumbricus terrestris</u>) ^(d)	7100		22.5
Bobwhite Quail (<u>Colinus virginianus</u>) ^e		85.7	27.5

[Studies F 10082^(a), F 10182^(b), C02382^(c), W01082^(d), A03680^(e)]

Submitted by Elanco May 1983

Phytotoxicity:

Field studies reported in the 1978 Draft Environmental Impact Statement reported that field studies revealed no monensin related phytotoxicity. Manure from cattle fed 40g monensin/ton were added to soil at the rate of 22 tons/acre and plant species were grown on the soil. This level of disposal caused no monensin-related phytotoxicity. Plant species studies were oats, sorghum, soybean, barley, sugarbeet, corn, tomato, cotton, cucumber, wheat, rice, pepper, alfalfa, fescue. Plants grown from seeds in soil which had been mixed with manure-containing monensin showed no phytotoxicity.

Overall Assessment

The projected use of monensin to prevent coccidiosis in goats caused by several species of the genus Eimeria should have no observable effects upon the environment where used. The levels added to the environment would be many times below levels capable of causing any temporary effects. Levels disposed of have little potential of affecting non-target species and accumulation and or biomagnification is extremely doubtful

Preparation of the Assessment

This assessment was prepared by Dr. Stanley E. Katz, Professor of Microbiology and Chairman, Department of Biochemistry and Microbiology, Cook College, New Jersey Agricultural Experiment Station, Rutgers University, New Brunswick, New Jersey

REFERENCES

Donoho, A.L. 1984. Biochemical Studies on the Fate of Monensin in Animals and the Environment. Jour. of Animal Sci. 58: 1528-1539.

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Draft Environmental Impact Statement Subtherapeutic Antibacterial Agents in Animal Feeds (1978) Food and Drug Administration, Dept of Health, Education and Welfare. Rockville, MD 20857