Environmental Assessment

1. Date: July 20, 1993

2. Name of applicant or petitioner: Pfizer Inc, North Aminal North American Animal Health Division

3. Address: 1107 S. State Route 291, Lee's Summit, MO 64081-2998

4. Description of the proposed action:

This Environmental Assessment is required for a claim addition to NADA #92-444 for Rumatel 88 (morantel tartrate) Type A Medicated Articles, and is descriptive of environmental concerns related to the blending and packaging of these products.

5. Identification of the chemical substances that are the subject of the proposed action are:

The chemical substance Morantel Tartrate CAS # 26155-31-7 is the subject of the proposed action. Morantel Tartrate is the active ingredient in Rumatel 88 (morantel tartrate) Type A Medicated Articles.

6. Introduction of substances into the environment for the Lee's Summit, MO site of the manufacture of the Rumatel 88 (morantel tartrate) Type A Medicated Articles:

a. List of substances expected to be emitted:

Liquid substances	Chemical Abstract Registry No.
Aqueous Cleaning Solution consisting of:	
Calcium carbonate	1317-65-3
Food grade oil	8001-22-7
Morantel Tartrate	26155-31-7
Rice hulls	none
Sodium aluminosilicate	1344-00-9
Trisodium Phosphate	7601-54-9
Water	7732-18-5
Gaseous substances	
Air contaminated with particulates of:	
Calcium carbonate	6804-07-5
Corn cobs	none
Food grade oil	8001-22-7
Morantel Tartrate	26155-31-7
Rice hull dust	none
Sodium aluminosilicate	1344-00-9

a. List of substances expected to be emitted: (continued)

Solid wastes	Chemical Abstract Registry No.
Cleanout materials that could consist of:	
Calcium carbonate	6804-07-5
Corn cobs	none
Food grade oil	8001-22-7
Morantel Tartrate	26155-31-7
Rice hulls	none
Sodium aluminosilicate	1344-00-9
Dust collector filter bags	none
Dust from dust collector consisting of:	
Calcium carbonate	6804-07-5
Food grade oil	8001-22-7
Morantel Tartrate	26155-31-7
Rice hull dust	none
Sodium aluminosilicate	1344-00-9
Empty raw material containers	none
Floor sweepings	none
Personnel protective clothing	none
Rumatel 88 (morantel tartrate)Type A Medicated Articles	none
Rejected raw materials consisting of:	
Calcium carbonate	6804-07-5
Food grade oil	8001-22-7
Morantel Tartrate	26155-31-7
Rice hulls	none
Sodium aluminosilicate	1344-00-9

b. Description of controls used to limit or eliminate emissions:

Liquids

Since the blending and packaging of Rumatel 88 (morantel tartrate) Type A Medicated Articles is a dry process, the equipment and transfer lines are typically precleaned with a dry cleanout material. But on an infrequent basis, components of equipment and transfer lines may be cleaned with an aqueous cleaning solution. All of the contaminated aqueous cleaning solutions are disposed of by incineration off site or by sending to the Little Blue Valley Sewer District (the local POTW) for treatment. The precleaning of the system with dry cleanouts material ensures that the quantity of morantel tartrate present in the wastewater will be minimal.

Gaseous substances

Particulate emissions from the Rumatel 88 (morantel tartrate) Type A Medicated Articles blending and packaging operation are controlled by a dust collection system using baghouse type air filters. All the ingredients for Rumatel 88 (morantel tartrate) Type A Medicated Articles are solids, with the exception of a minor amount of food

grade oil. Emissions of particulate matter during the transfer of ingredients are controlled by baghouse type air filter receivers.

Solid wastes

Solid wastes from the Rumatel 88 (morantel tartrate) Type A Medicated Articles blending and packaging operation are special solid wastes. The dry special solid wastes consist of equipment cleanout materials, empty raw material containers, floor sweepings, personnel protective clothing, dust collector filter bags, dust from the facility's dust collection systems, rejected raw materials and out-of-date Rumatel 88 (morantel tartrate) Type A Medicated Articles. The dry cleanout materials used to preclean the system, along with add back materials, may be recycled into a subsequent production batch of Rumatel 88 (morantel tartrate) Type A Medicated Articles or disposed of in accordance with federal and state regulations. The above special solid wastes are disposed of in a secure landfill or by incineration.

c. Citation of the applicable Federal, state, local (and foreign) emission regulations and laws (including occupational) at the site:

Liquids

The wastewater from the site is discharged into the Little Blue Valley Sewer District's Publicly Owned Treatment Plant (POTW). Discharge from the blending and packaging facility is in compliance with Industrial User Discharge Permit #LB-0495-LS205 or its successor as required by the Little Blue Valley Sewer District's Regulations of Use. All the above are under the Clean Water Act's General Pretreatment Standards 40 CFR Parts 403 and Missouri Clean Water regulations 10 CSR 20-6.

Gaseous substances

Particulate emissions are controlled to be in compliance with the Clean Air Act and the Clean Air Act Amendments codified in Federal regulations 40 CFR Parts 50, 52 and 60 and the Missouri Air Pollution Control Regulations of 10 CSR 10-2 & 10-6.

Solid wastes

The above special solid wastes are disposed of in a secure landfill or by incineration covered by Federal Regulations 40 CFR Parts 240 to 258 and Missouri Solid Waste Rules 10 CSR 80.

Occupational

Occupational exposure to air contaminants during the blending and packaging operations is limited since the operation is contained within a closed system. Monitoring of the work area to ascertain occupational exposure will be done on a routine basis and all exposure to listed chemicals will be controlled to maintain compliance with OSHA standards in 29 CFR 1910.1000. The Lee's Summit, Missouri site makes available to its employees the appropriate detailed Material Safety Data Sheets (MSDS) for the raw materials used in the

plant and Rumatel 88 (morantel tartrate) Type A Medicated Articles equivalent to OSHA's Form 20.

d. Statement certifying compliance with the cited requirements.

Information in Section 6. constitute a citation of, and statement of compliance with, applicable emission requirements pursuant to 21 CFR 25.31a.

e. Discussion of the effects that approval will have upon compliance with current emission requirements and an estimate of the maximum yearly market volume of the drug product.

The North American Animal Health Division, Pfizer Inc does not anticipate a change in compliance with current emission requirements as a result of this action. The Rumatel 88 (morantel tartrate) Type A Medicated Articles is currently being blended and packaged in the existing premix plant.

An estimate of maximum yearly production volumes of Rumatel 88 (morantel tartrate) Type A Medicated Articles is 200,000 pounds.

7-11. According to the Environmental Assessment Format provided, documentation for items 7-11 on the EA format in 21 CFR 25.31a need not be provided.

12. List of preparers:

The following are all members of the staff of the North American Animal Health Division, Pfizer Inc Lee's Summit, MO.

Richard H. Bartel B.S., P.E.

Manager of Environmental Compliance, North American Animal Health Division, Lee's Summit, MO plant. B.S. in Chemical Engineering; 30 years of experience in chemical manufacturing and environmental engineering.

John Horigan DVM

Manager of Regulatory Affairs, North American Animal Health Division, Lee's Summit, MO plant. Doctor of Veterinary Medicine; 15 years experience in the North American Animal Health field.

Jay J. Rash PhD

Director of Regulatory Affairs, North American Animal Health Division, Lee's Summit, MO plant. Ph.D. in Analytical Biochemistry; 20 years experience in the North American Animal Health industry.

13. Certification

This is to certify that the information presented herein is true, accurate and complete to the best of Pfizer Inc's knowledge concerning the Environmental Assessment of the blending and packaging of Rumatel 88 (morantel tartrate) Type A Medicated Articles in Pfizer Inc's existing premix plant at Lee's Summit, Missouri.

July 20, 1993

Richard H. Bartel, P.E.
Manager of Environmental Compliance

MSDS

ISSUE DATE: 3/86

MATERIAL SAFETY DATA SHEET
"ESSENTIALLY SIMILAR" TO OSHA FORM 20

MANUFACTURER/ADDRESS
Pfizer Chemical Division
235 East 42nd St.
New York, N.Y. 10017

PRODUCT IDENTIFICATION

PFIZER PRODUCT NAME: Morantel Tartrate [redacted]

PFIZER MSDS NO.: 3024

EMERGENCY PHONE NUMBER(S): (718)-780-8456

CHEMICAL NAME AND MOLECULAR FORMULA: 1,4,5,6-Tetrahydro-1-methyl-2-[trans-2-(3-methyl-2-thienyl) vinyl]-pyrimidine tartrate) [illegible]

CAS NO.(S): 20155-31-7

SYNONYMS:

CHEMICAL FAMILY:

HAZARDOUS COMPONENTS

MATERIALS OR COMPONENTS	%	HAZARD DATA (TLV, LD50, LC50, etc.)
Material is a single component entity.		

PHYSICAL PROPERTIES

BOILING POINT (°F)	Not Applicable	SPECIFIC GRAVITY (H_2O = 1)	
VAPOR PRESSURE (mm Hg.)	Not Applicable	PERCENT VOLATILE BY VOLUME (%)	<1% (water)
VAPOR DENSITY (AIR = 1)	Not Applicable	EVAPORATION RATE (water = 1)	=
SOLUBILITY IN WATER	Appreciable	pH % SOLN	
APPEARANCE & ODOR	Pale yellow to pale greenish-yellow powder.		

FIRE & EXPLOSION DATA

FLASH POINT (Method used)	Not Determined	FLAMMABLE LIMITS Explosive Conc.	min Lel 1g/ft³	opt.Uel 40g/ft³
EXTINGUISHING MEDIA	Water, CO_2, foam or spray.			
SPECIAL FIRE FIGHTING PROCEDURES	Oxides of carbon, sulfur or nitrogen may form, requiring mask.			
UNUSUAL FIRE AND EXPLOSION HAZARDS	Rated "strong" by G. of M. severity rating system.			

REACTIVITY DATA

STABILITY	UNSTABLE		CONDITIONS TO AVOID: Avoid exposure to light.
	STABLE	XX	
INCOMPATIBILITY (Materials to avoid)	None Known		
HAZARDOUS DECOMPOSITION PRODUCTS	Oxides of carbon, nitrogen and sulfur may form on burning.		

HAZARDOUS POLYMERIZATION		CONDITIONS TO AVOID
May Occur	Will Not Occur	
	XX	Not Applicable

CITY

ORAL/PARENTERAL
orl-rat LD_{50}: 926mg/kg; orl-mus LD_{50}: 300mg/kg; ipr-mus LD_{50}: 20mg/kg.

DERMAL (acute)
Not Available

EYE	INHALATION
Not Available	Not Available

CHRONIC

Tolerances for residual morantel tartrate in cattle have been established at 0.5 ppm in uncooked cattle muscle, 1.0 ppm in liver, 1.5 ppm in kidney and 2.0 ppm in fat. 21CFR556.425.

HEALTH HAZARD INFORMATION

Effects of Exposure

ORAL INGESTION
Effects not determined -- dependent on amount ingested.

EYE CONTACT
May be an irritant.

SKIN CONTACT
May be an irritant with resultant dermatitis.

INHALATION
See Oral Ingestion.

Emergency First Aid

ORAL INGESTION
Induce vomiting. Get medical attention.

EYE CONTACT
Wash contacted eye with copious volumes of water for at least 15 minutes. Get medical attention if irritation persists.

SKIN CONTACT
Wash contaminated area with plenty of water. Get medical attention if irritation persists. Launder clothing before reuse.

INHALATION
Remove person to fresh air. Get medical attention if person is suffering discomfort and/or faintness.

SPILL, LEAK

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED

Scoop/sweep/vacuum into recovery containers. Wear dust mask to minimize inhalation of dusts. Flush area with water to remove final traces.

WASTE DISPOSAL METHOD (Comply with applicable federal, state, and local regulations.)

Comply with applicable federal, state and local regulations. Consider controlled incineration.

SPECIAL PROTECTION INFO.

RESPIRATORY PROTECTION (Specify type)
Dust Mask

VENTILATION			
	LOCAL EXHAUST	Sufficient to control	SPECIAL
	MECHANICAL (general)	dust.	OTHER

PROTECTIVE GLOVES
Normal work gloves.

EYE PROTECTION
Safety Glasses

OTHER PROTECTIVE EQUIPMENT
None Required

SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING

Store in a cool dry place, protected from light.

OTHER PRECAUTIONS

None Required

ENVIRONMENTAL IMPACT ASSESSMENT

THE USE OF MORANTEL TARTRATE TO TREAT GASTROINTESTINAL PARASITE INFESTATIONS IN GOATS

March 1991

Description of Proposed Use

Morantel tartrate is proposed for the treatment of lactating dairy goats for gastrointestinal parasites as a single oral treatment of 4.4 mg morantel tartrate (equivalent to 2.7mg morantel base) /lb body weight.

Gastrointestinal parasites such as Haemonchus contortus, Trichostrongylus Axei and Teladorsia circumcincta among others can infect the intestinal tract of the goat. this can cause inhibition of the host appetite, a decrease in the digestability, anemia and occasionally death of animals. The exact symptomology is based upon the specific parasitic infection involved. Most of the problems of internal parasitism are chronic and the main problem is lack of efficiency of feed conversion and losses in milk production.

Chemical Structure and Properties

Morantel tartrate: CAS Nomenclature and number [26155-31-7] 1,4,5,6-tetrahydro-1-methyl-2-[trans-2-(3-methyl-2-thienyl)vinyl] pyrimidine tartrate(1:1). Morantel base has the CAS number 20574-50-9

Chemical Formula: Morantel tartrate- $C_{16}H_{22}O_6N_2S$

Morantel - $C_{12}H_{16}N_2S$

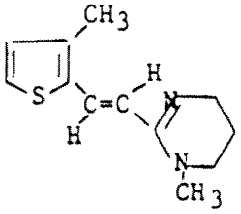
Molecular Weight: Morantel tartrate- 370.4

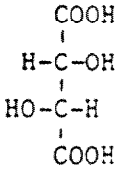
Morantel - 220.3

Melting Point: Morantel tartrate: 170-174°C

Morantel: 239-240°C

Structural Formula:





Morantel Tartrate $C_{16}H_{22}O_6N_2S$ RN=26155-31-7 Mol. wt. 370.4

Physical/ Chemical Biological Properties of Morantel Tartrate

a. Water solubility - Morantel tartrate 150 mg/mL.

b. Solvent solubility - It is readily soluble in methanol but solubility is diminished in non-polar solvents. Distribution of morantel tartrate from water into a non-polar organic solvents is negligible except at pH values of 9 or higher.

c. Octanol/Water partition coefficient - < 0.1

d. Aqueous half-life in 366 nm light - 9.1 h

Introduction Into The Environment

Lactating dairy goats will be treated for gastrointestinal parasites with a single oral dose of 4.4 mg morantel tartrate (equivalent to 2.7 mg morantel base)/lb body weight.

Morantel tartrate will be introduced into the environment through excretion, primarily in the feces. Approximately 74% of the oral dose is recovered on the feces with 60% being unchanged; some 14% was found in the urine, none being unchanged. Peak levels in milk occurred at the time of the second milking. Within 96 h, essentially all morantel tartrate, either unchanged or metabolized is excreted.

Assumption Upon Which This Assessment Is Based

For the assessment, the following assumption were used:

1. This assessment uses a 250-animal herd model which would rank a the top of herd sizes.

2. It is assumed that all the animals in the herd are lactating and will be treated at the same time with a single oral dose of 4.4mg morantel tartrate/lb body weight.

3. All the lactating goats weigh 70 kg or 154 lbs.

4. All the morantel tartrate and metabolites will be excreted in the feces, urine and milk in 96 h.

5. All animals will be housed and treated in one area. The bedding, excreta and milk will be removed from the treatment area and disposed at one time by plowing into the soil.

6. It will be assumed that none of the morantel tartrate and metabolites will degrade prior to the soil disposal.

7. Each animal will eat a total of 4 lbs of ration per day and will excrete 2 lbs of solid excreta and 8 lbs of liquid waste and 3 lbs of milk per day for 5 days. It will also be assumed that the animals will use the stall for an additional 2 days.

8. Each animal will be provided with 25 lbs of bedding for the treatment period and 2 additional days until the stall is cleaned. The bedding material will be plowed-in to the soil with the solid and liquid wastes and the discarded milk.

9. Two plow-in rates will be used, 5 and 10 tons/acre. The plow-in depth will be 6 inches.

Soil Disposal

Concentration of Morantel Tartrate in Wastes

4.4 mg morantel tartrate/ lb x 154 lbs/goat x 250 goats x 1000 ug/mg = 169,400,000 ug morantel tartrate used and excreted. Equivalent to 103,950,000 ug of morantel base.

250 animals x 2 lbs solid excreta/goat/day x 7 days = 3,500 lb

250 animals x 8 lbs liquid waste/goat/day x 7 days = 14,000 lb

250 animals x 3 lbs milk/goat/day x 5 days = 3,750 lb

250 animals x 25 lbs bedding/goat = 6,250 lb

Total Waste = 27,500 lb

Assuming that all the morantel tartrate is excreted unmetabolized from the animals, the concentration in the waste produced would be:

169,400,000 ug morantel tartrate/27,500 lbs x 454 g/lb = 13.57 ug morantel tartrate/g waste = 13.57 ppm. This is equivalent to 8.32 ug morantel base/g waste = 8.32 ppm.

Concentration of Morantel Tartrate in Soil After Disposal

a. At 5 tons waste/acre.

[27,500 lbs/ 2000 lbs/ ton x 5 tons/acre] x 43,560 ft^2/acre x 144in^2/ft^2 x 6" depth x 16.4 cm^3/in^3 x 1.5 g/g soil density = 169,400,000 ug morantel tartrate / 2,546,064 756 g soil = 0.066 ug morantel tartrate / g soil = 0.066 ppm.

This is equivalent to 0.041 ppm morantel base

b. At 10 tons waste per acre.

The calculated concentrations for this level of disposal are: 0.132 ug morantel tartrate / g soil = 0.132 ppm

0.082 ug morantel base / g soil = 0.082 ppm.

Biodegradation in Soil

In the EIA report for morantel tartrate, NADA # 92-444,NADA # 93-903, 1 November 1979, it was stated that microbiological degradation studies were not performed. Because of the lack of data, the evidence presented in those NADA report will be reviewed.

The lack of any significant antimicrobial activity of morantel tartrate resulted in the statement that it would be a good substrate for microbial degradation. This can or cannot be the case. Lack of any significant antimicrobial activity is not a indicator or criterion for biodegradation.

The morantel tartrate offers 4 sites for degradation. The tartrate moeity is readily degradable since it undergoes many biochemical transformations. There is no doubt that that portion of the molecule will be degraded. The morantel base portion of the molecule offers 3 sites for possible degradation: the thiophene moeity, the >C=C< portion and the pyrimidine function. Each part of the molecule is discussed individually.

a. Thiophene - The microbial degradation of thiophene and methyl thiophene by Pseudomonas aeruginosa isolated from soil was reported. The 2-methyl thiophene was 41% degraded and 3-methyl thiophene was 87% degrade in 4 days. The products of the degradation of thiophene-2-carboxylate were SO_4 and 2-oxyglutaric acid. It appears that this portion of the molecule can be attacked by microorganisms found in the soil.

b. >C=C< bond - There is no doubt that the >C=C< bonds can be transformed by several mechanisms: (1) formation of epoxides

which in turn can be converted to diols, (2) hydration of the double bond to produce a mono alcohol and (3) direct transformation to diols followed by hydrolysis. There is little doubt that this portion of the molecule can be attacked by microorganisms.

c. Pyrimidine - Pyrimidines can be transformed by (1) hydroxylation, (2) cleavage of the ring, (3) reduction of double bonds, (4) formation of phase 2 derivatives such as ribose derivatives. Some of the organisms capable of these transformations are: Norcardia corrallen, Corynebacterium spp., Brevibacterium ammoniagenes and Zymobacterium oroticum. There is little doubt that the pyrimidine portion of the molecule can be attacked by soil microorganisms.

Although the molecule has every potential for degradation, there is no data on the rate of degradation. Both the free base and the tartrate form should degrade at any of 3 points, excluding the tartrate. Morantel should readily degrade in the soil. The only question that remains is the rate. The calculated low levels resulting from the proposed use, 0.066 ppm at the 5 ton/acre disposal level and 0.132 at the 10 ton/acre level should pose no long term problem.

Potential for Run-off

Morantel tartrate has a high solubility in water, 150 mg/mL. The base is also quite soluble. Considering this solubility and the lack of soil adsorption data, it must be assumed that morantel tartrate will migrate quite readily in soils and the potential for run-off/leach will be high. Assuming that all the morantel tartrate from the disposal site would leach into an acre

-inch of water, the concentration in the acre-inch would be: 169,400,000 ug morantel tartrate / 1 acre x 43,560 ft^2/acre x 144 in^2/ft^2 x 1" depth x 16.4 cm^3/in^3 = 1.647 ug morantel tartrate/ml water = 1.647 ppm. The corresponding concentration for morantel base is 1.01 ug morantel base/ml water or 1.01 ppm

If the morantel tartrate were to leach into a 1-acre farm pond having a depth of 3 ft, the concentration in the pond would be:

1 acre x 43,560ft^2/acre x 144in^2/ft^2 x 36" depth x 16.4 cm^3/in^3 = 0.046 ug morantel tartrate/mL water = 0.046 ppm. The corresponding concentration of the morantel base = 0.028 ppm.

If the morantel tartrate in the acre-inch of water were to flow into a small stream, 10 ft wide, having an average depth of 3 ft and a flow of 1 foot/min, over a 24-h period, the concentration in the stream plug would be:

169,400,000 ug morantel tartrate / 24 h x 60 min/h /10 ft wide x 12 in/ft x 12 in plug x 36 in depth x 16.4in^3 =0.057 ug or ppm morantel tartrate which is equivalent to 0.035 ppm morantel base.

If one considered dilution factors in the stream over time of between 100 and 1000, the already low concentration becomes quite negligible.

Photodegradation

There is a rapid photochemical conversion of the morantel tartrate by 366 nm light to the biologically inactive cis form. The half-life is estimated to be 9.1 minutes. Essentially complete conversion of the molecule to the biologically inactive form should occur before any potential harmful effect could be

manifested. An example of this would be to take the concentration of 1.647 ppm morantel tartrate in the hypothetical acre-inch of water through 10 half-lives of 9 min. After 90 min, the concentration of the morantel tartrate in the water would be 0.0033 ppm. Photodegradation in the aquatic system is a very powerful mechanism of conversion of the active trans form of morantel to the biologically inactive cis form.

Effects on Microorganisms

There are limited data on the effects of morantel tartrate or the corresponding base on bacteria. There are no reported inhibitory effects upon bacteria. Proposed metabolites such as 3-methyl-2-thienyl acrylic acid showed no activity at a level of 100 ug/ml against E. coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa and Stapylococcus aureus. N-(3-methyl aminopropyl)-3-(3-methyl-2-thienyl) acrylamide was inactive at a level of 25 ug/mL against Streptococcus pyogenes, E. coli, Klebsiella aerogenes, Shigella sonei, Shigella flexii, Proteus vulgaris, Proteus mirabilis and Pseudomonas aeruginosa. This lack of activity at the specified levels indicated a low potential for breakdown products to influence soil microbial processes.

Interferences with Microbially-Mediated Soil Processes

The lack of activity of morantel tartrate and some proposed metabolites against many common bacterial genera leads to the suggestion that interference with the microbially-based processes of the soil such as nitrification, denitrification, nitrogen fixation, sulfur and phosphorus solubilization and biodegradation of carbon compounds should be minimal to non-existent. The levels

of no activity are at least 189 times greater than the highest level calculated for the 10 ton / acre disposal level. This calculation counterbalances the fact only data for a limited spectrum of genera, many associated with pathogenicity in humans, was provided.

Effect on Plant Growth

There appears to no evidence of phytotoxicity for morantel tartrate or its corresponding base. Morantel applied at the rate of 15 lb / acre to tomato and cucumber plants caused phytotoxic effects. Bean plants and sugar beets were unaffected by levels of 50 lbs morantel / acre.

These limited data indicate that the highest calculated plow-in levels are far below the tested levels. The 50 lb morantel/acre translates to a soil level in the top inch of 147 ug morantel/g soil; the 15 lbs /acre translates to 44.1 ug morantel/g soil. The highest level of morantel calculated for the soil was 0.132 ug/g a fact of 1114 times less than the 50 lb rate of application and 334 times less than the 15 lb/acre application. There should be no phytotoxic effects from soil disposal of morantel tartrate.

Effects Upon Non-Target Species

Morantel tartrate appears to have low potential for toxicity. The following summary of acute toxicities indicate this low potential.

COMPOUND	SPECIES	TOXICITY	ROUTE
Morantel Tartrate	Rat	LD_{50}>990 mg/Kg	oral
	Mouse	LD_{50}>300 mg/Kg	oral
	Rat	NOEL 50 mg/Kg	oral
	Rat	Chronic > 20 mg/Kg	oral
	Dog	Chronic > 10 mg/Kg	oral
1,3 propanediamine	Rat	LD_{50} 350 mg/Kg	oral
N,N,dimethyl-1,3 propanediamine	Rat	LDLo 1870 mg/Kg	oral
2-methyl thiophene	Mouse	LDLo 500 mg/kg	IP
3-methyl thiophene	Mouse	LDLo 512 mg/Kg	IP

Plow-in disposal has the potential for disrupting other helminth species. Morantel tartrate is effective in inhibiting the fumarate reductase system which acts as a respiratory chain in many helminths. The calculated soil levels of morantel tartrate of 0.132 ppm (0.082 morantel base) at the 10 tons/acre disposal level is quite low. It is doubtful that this level could cause any significant effects upon non-target organisms such as earth worms.

Effects Upon Aquatic Species

The effects of morantel tartrate on two test species indicates a low potential for effects.

Species	Name	TL_m ppm
Cyprinus carpio	Carp	> 2,000
Monia macrocopia	Water flea	8,400 (3h)
		7,100 (6h)
		5,600 (24h)

These levels are at least 1200 times greater than the concentration in the hypothetical acre-inch of water. From these calculations, there appears to be little potential for harm in the aquatic ecosphere.

Hydrolysis in Water

There were no data available on the chemical hydrolysis of morantel tartrate or the corresponding base in water. Stability

is precluded by the rapid rate of photoconversion to the biologically inactive cis form.

Biomagnification

The octanol/water partition coefficient of 0.1 indicates a very low potential for biomagnification. This coupled with the very polar nature of the tartrate salt and the free base preclude any significant biomagnification.

Overview

There does not appear to be any potential for disruption of the disposal area and environs from the proposed use of morantel tartrate to treat intestinal parasites in lactating goats. Although the data provided for the assessment was developed in the 1970's, and was lacking in many areas, there was sufficient information to make a reasonable assessment of no significant impact.

The morantel molecule had 3 sites for biodegradtion in soil or in microbial systems, excluding the tartrate portion. The rate of degradation is unknown but should be sufficiently rapid to ensure that there would be no buildup in soil. The photochemical lability of morantel should prevent any possible effects upon fish. There is little potential for biological magnification. There should be no observable effects upon microbially-mediated processes. Because of the specificity of mechanism of action of morantel tartrate against helminths, there should be no effects on non-target species.

Preparation of the Environmental Assessment

This assessment was prepared by Dr. Stanley E. Katz, Research Professor, Department of Biochemistry and Microbiology, Cook College/NJ Agricultural Experiment Station, Rutgers-the State University of New Jersey, New Brunswick, NJ 08903-0231.

References

The Merck Index, Eleventh Edition, 1989, Merck & Company, Rahway NJ

Environmental Impact Analysis Repart for Morantel Tartrate, 1979. NADA # 92-444, NADA # 93-903