ENVIRONMENTAL ASSESSMENT

NADA 139-472

1. **DATE:** July 11, 1988

2. **NAME OF APPLICANT:**

Fermenta Animal Health Company

3. **ADDRESS:**

7410 NW Tiffany Springs Parkway
P.O. Box 901350
Kansas City, Missouri 64190-1350

4. DESCRIPTION OF PROPOSED ACTION

The proposed action is the manufacture of DENAGARD® (tiamulin)* premixes and their use in swine for the control of swine dysentery associated with Treponema hyodysenteriae and increased rate of weight gain and feed efficiency.

Fermenta Animal Health is not the manufacturer of the technical material but will manufacture the drug premix (25% tiamulin) at its Princeton, New Jersey facility, and lower premix levels at toll blenders.

DENAGARD is administered in the feed of swine to control swine dysentery or improve growth and feed efficiency.

DENAGARD is added to swine feed at the rate of 35 grams tiamulin per ton on a continuous basis from weaning to market weight for the control of swine dysentery. For improved rate of weight gain and feed efficiency, in the absence of disease, DENAGARD is fed to swine at 10 grams tiamulin per ton of feed from weaning to market weight.

Purpose of Action

The direct purpose of the action of this drug is to control a debilitating and frequently fatal disease of swine and, when disease control is not a factor, to improve growth and feed efficiency.

The ultimate purpose is to increase the availability of pork for human consumption. Other economic benefits are:

- Reduce the cost of pork production
- Reduce the cost of pork to the consumer.

The Affected Environment

The environment to be affected if the action is taken is described as follows:

- Food Supply
  An increased supply of pork should be available at a reduced cost of production.
- Manufacturing Site
  The manufacturing process is designed to minimize or, where possible, eliminate waste. No potentially dangerous air or water emissions are produced.

*In this Environmental Assessment, tiamulin refers to tiamulin hydrogen fumarate.

5. IDENTIFICATION OF CHEMICAL SUBSTANCES THAT ARE THE SUBJECT OF THE PROPOSED ACTION

Nomenclature
Tiamulin hydrogen fumarate (Tiamulin)

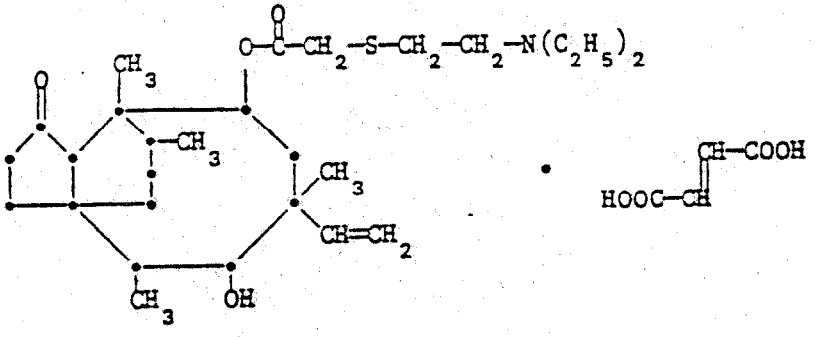
[(2-(Diethylamino)ethyl)thio]acetic acid 6-ethenyldecahydro-5-hydroxy-4,6,9,10-tetramethyl-1-oxo-3a, 9-propano-3aH-cyclopentacycloocten-8-yl ester

14-desoxy-14-[(2-diethylaminoethyl) mercaptoacetoxy]mutilin

CAS Registry Number
55297-96-6

Molecular Weight
609.8

Structural Formula



Physical Description

- Appearance
  Fine crystalline powder
- Color
  White to off-white; may be yellow-white
- Melting Range
  146±3 C

Additives
None

Impurities
Not more than 3%

6. INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT

Information on the environmental assessment of the manufacturing process for DENAGARD Antibiotic Premix (25% tiamulin) at the Princeton, NJ, facility follows::

Identification of pollutants expected to be emitted

- Tiamulin hydrogen fumarate (14-Deoxy-14- (2 diethyl-aminoethyl) mercaptocetoxy mutilin hydrogen fumarate)
- Isopropyl alcohol
- Poly(vinyl chloride)

A citation of applicable Federal, state, and local emission requirements

The State of New Jersey, Department of Environmental Protection has the authority to regulate air emissions, effluent water discharges, and disposal of solid waste. No Federal or local regulations will be cited.

o The applicable standards for emissions are N.J.A.C. 7:27-6.2.

7:27-6.2 - Standards for the Emission of Particles

(a) No person shall cause, suffer, allow or permit particles as measured by the performance test principles set forth in Section 3 of this subchapter to be emitted from any source operation, except as provided in subsection (b) of this section, through any stack or chimney into the outdoor air in excess of the maximum allowable emission rate as determined below:

Maximum Allowable Emission Rate for Particles

Potential Emission Rate From Source Operation (lbs per hr)	Allowable Emission Rate (lbs per hr) Based on 99% Efficiency of Collection	Source Gas Emitted From Source Operation (Standard cu ft per min)	Allowable Emission Rate (lbs per hr) Based on 0.02 grains per SC
50 or less	0.5	3,000 or less	0.5
100	1.0	6,000	1.0
1000	10.0	35,000	6.0
2000	20.0	70,000	12.0
3000 or greater	30.0	140,000	24.0
		175,000 or greater	30.0

Instructions

1. From Columns 1 and 2 above, determine the allowable emission rate based upon the potential emission rate of particles from the source operation as measured by the performance test principles set forth in subsections 3(a) and 3(b) of this subchapter;

2. From Columns 3 and 4, determine the allowable emission rate based upon the source gas emitted from the source operation. Whenever dilution gas is, for any purpose, added to the source gas from a source operation, the source gas emitted shall be considered to be the gas discharge rate prior to such dilution;

3. The greater of the two emission rates as determined from Columns 1 and 2 shall be the maximum allowable emission rate. For rates between any two consecutive values stated in Columns 1 and 3, the corresponding allowable emission rates shall be as determined by interpolation.

- The standard regulating the emission of isopropanol is N.J.A.C. 7:27-16.6. The process equipment is designed to exceed the required 88 percent recovery of isopropanol.

- The standard for effluent water discharges is N.J.A.C. 7:14A-1 et. seq.

- The disposal of solid wastes generated from the process is regulated by N.J.A.C. 7:26.

- The possibility of water pollution exists through two routes. The first is direct discharge to surface water. The plant operates under NJPDES permit number NJ0004502. This provides for the discharge of non-contact cooling water from various operations within the plant.

  The only connections to this system in the process area will be permanent connections not subject to alteration or change by operating personnel. Therefore, no contamination of water discharged through the NJPDES discharge is possible. Indirect discharge through the local sewage authority is governed by a contract rather than local statute. The only limit which applies is on the loading for biological oxygen demand (BOD).

  From the tiamulin process, some water will enter the sewage system from cleaning operations. Washing will be preceded by thorough emptying of vessels and vacuuming where possible.

  The process water which is evaporated and recovered as a mixture with isopropanol will be treated as a separate waste stream. The material will either be recycled off-site to recover the isopropanol or incinerated also off-site. The increase in BOD loading is insignificant.

  The direct discharge to surface water is controlled by engineering design. Indirect discharge is controlled by requirements of accountability and work procedures. There will be no contamination of surface water.

A small amount of solid waste will be generated from the tiamulin process. This will be from cleanup, aborted batches and returned goods. It has always been standard practice at the Princeton Plant to treat any drug-related wastes as hazardous even though not required. This means that these wastes are handled in separate containers within the plant and are ultimately sent to a secure landfill. Resource Conservation and Recovery Act requirements for inventories, inspections, training and manifesting are all followed.

In summary, emissions will comply with the applicable requirements.

- Occupational Standards
  Although no specific limit has been set by OSHA for exposure to tiamulin, personnel who handle the technical product will be protected from potential inhalation and dermal hazards. The established industrial hygiene limits on isopropanol exposure will be monitored and controlled.

- Alternate Sites
  An environmental assessment of the manufacturing process at toll blending sites reveals that the only pollutant expected is dust, since the lower premix levels are prepared from the 25% standardized tiamulin premix (DENAGARD Antibiotic Premix) manufactured by Fermenta Animal Health Co., Princeton, NJ. Since the identity of toll blenders (alternate manufacturing sites) is confidential information, certification statements from the blenders are found in Section 5(xiii) of the NADA. The blenders have adequate dust control equipment. Occupational exposure to tiamulin is minimized by use of appropriate protective clothing and/or dust masks.

7. FATE OF EMITTED SUBSTANCES IN THE ENVIRONMENT

Where Drug Will Be Used
DENAGARD is intended for use in the control of swine dysentery and to improve rate of weight gain and feed efficiency when disease prevention is not a factor.

Swine dysentery is one of the major swine diseases. According to a recent survey, 42.5 million animals were treated for swine dysentery including preventive treatments. Treatment was with feed, water and injectable products, with approximately 37 million animals receiving preventive medication. It is anticipated that, at market maturity, DENAGARD will be used to treat about 20 percent of the swine currently treated by medication for the prevention of swine dysentery, that is, approximately 7.4 million animals treated per year. At the concentration of 35 g/ton of feed, this translates to 24,000 kg of tiamulin per year for swine dysentery control.

The anticipated use of tiamulin for growth promotion and improved feed efficiency is more difficult to assess since many antibiotics are fed for both disease prevention and growth promotion and improved feed efficiency. However, it seems reasonable to assume that with both claims the anticipated use of tiamulin would double to an annual use rate of 48,000 kg of tiamulin.

For the prevention of swine dysentery, the level of tiamulin in the feed is 35 g/ton and for growth promotion and improved feed efficiency 10 g/ton. It is recommended that in both instances tiamulin will be fed continuously from weaning to market weight.

Based on these uses and the population and incidence rates cited above, it is estimated the annual use rate of tiamulin will be about 48,000 kg of active drug.

Fate of Drug in Swine

Studies to determine the metabolism of tiamulin in swine reveal the following:

- Greater than 85 percent of an oral dose is absorbed by swine.
- A steady state of uptake and excretion of tiamulin is reached in less than 5 days.
- After oral administration of radiolabeled tiamulin, concentrations of radioactivity in blood reached a maximum within 2-4 hours after dosing.
- Tiamulin is rapidly metabolized by swine and the metabolites are rapidly excreted, mainly in feces via bile.
- At least 25 metabolites are present in urine and bile; 16 of which have been structurally identified.
- During metabolism, tiamulin undergoes desalkylation, hydroxylation, oxidation and sulfoxidation. In addition, some metabolites are conjugated prior to excretion.
- Greater than 96 percent of a dose administered to rats is eliminated in the excreta within 48 hours after administration of the dose.
- The target organ in swine is liver. In less than 1 day after cessation of feeding DENAGARD at 35 g/ton (tiamulin), the mean value for the marker substance in the liver is less than half the established tolerance of 400 ppb.
- Any metabolism of tiamulin appears to greatly reduce its bioactivity. All of the metabolites which have been evaluated either have no detectable bioactivity or are much less bioactive than tiamulin against Sarcina lutea ATCC 9341.

- At the proposed use level of 35 g/ton, the mean residue level of tiamulin metabolites in tissues depletes rapidly to below the tolerance level in less than 1 day.

- Less than 0.5 percent of the dose is excreted in swine urine as parent compound.

- Studies with dogs have shown that, if one assumes no decomposition of the radioactive compounds from the bile by intestinal bacteria, then no more than 3 percent of the dose would be excreted in the feces as the parent compound. Studies with swine have indicated that tiamulin, if present in bile, must be in conjugated form.

Summarizing, the tiamulin absorbed by the animal is rapidly metabolized to a large number of products and eliminated mainly in the feces and to much lesser extent in the urine. The majority of these metabolites show little or no microbiological activity. Any potential environmental impact from the use of tiamulin can only result from spillage of medicated feed.

Amount of Drug in Feed Spillage

It is estimated that there is a maximum loss of 3% of swine feed due to spillage. The 3% value includes losses due to feed handling and spillage at the feeder by the pigs.

The estimated annual use rate of tiamulin in medicated feed is 48,000 kg; therefore, 3% is equal to 1440 kg of tiamulin lost due to spillage. Based on the estimated annual use of 24,000 kg of tiamulin at 35 g/ton for the control of swine dysentery, 700,000 tons of medicated feed will be produced. Similarly, for growth promotion and improved feed efficiency at 10 g/ton, 24,000 kg of tiamulin will produce 2.4 million tons of medicated feed.

For both uses (control of swine dysentery and growth promotion and improved feed efficiency) these quantities of feed will permit the medication of approximately 30 million pigs that would be expected to produce at least 40 million tons of waste per year.

Assuming equal distribution of 1440 kg of tiamulin throughout 40 million tons of swine waste, the mean concentration of tiamulin is 0.04 ppm. This is equivalent to 360 mg tiamulin per 10 tons of waste.

Fate of Drug in Feed Spillage

As noted earlier, essentially all of the tiamulin consumed by swine is converted to a large number of metabolites. No tiamulin can be found in any of the analyzed excreta. None of the tiamulin metabolites exhibit appreciable microbiological activity. Only tiamulin present in spilled medicated feed is of any possible environmental concern.

That the tiamulin present in spilled medicated feed might be of possible environmental concern is questionable for the following reasons:

(a) Air

- The vapor pressure of tiamulin is such that it would not be expected to enter the atmosphere. The vapor pressure determined at 100°C, 111°C, and 115°C was 2×10^{-5} torr, 4.5×10^{-5} torr, and 6.0×10^{-5} torr, respectively. Under extrapolation of these values, the vapor pressure of tiamulin was calculated to be 0.15×10^{-7} torr at 25°C, 0.49×10^{-7} torr at 35°C and 1.5×10^{-7} torr at 45°C.

- Photolysis: According to the first and second laws of photochemistry, light must be absorbed in order to affect photodegradation of a chemical compound. The absorption spectrum of the compound can, therefore, be used to predict the potential of the compound to photodegrade.

  The ultraviolet absorption spectrum of tiamulin in aqueous solution was determined. The data show that tiamulin absorbs light in the spectral region between 200 nm and 280 nm and absorbs no light in the wavelength region greater than 280 nm. Natural sunlight has very little energy in the wavelength region less than 280. It is predicted that, under conditions of natural sunlight, tiamulin will not photodegrade.

(b) Freshwater, estuarine, and marine ecosystems

- Tiamulin is freely soluble in water and it has been shown that the tiamulin in the DENAGARD premixes is solubilized in water within five minutes; therefore, tiamulin resulting from medicated feed spillage would be expected to be in aqueous solution from exposure to wash water and other sources of moisture in the housing environment.

- Adsorption/desorption data show that the binding potential of tiamulin is high and indicates that soil mobility is low. Therefore, based on these properties, tiamulin would not be expected to leach significantly or be subject to run off.

- In preliminary small-scale environmental impact studies it was shown that at 2.4 ppm in pond water, more than 80 percent tiamulin was lost when stored for 9 weeks at room temperature; 30 percent was lost when stored for 2 weeks at 37°C. At a concentration of 600 ppm in pond water, no loss of tiamulin was observed when stored for 3 months at room temperature; 40 to 50 percent loss was observed when stored for 10 weeks at 37°C.

  - Effect On Pond Flora and Fauna
    In preliminary small-scale environmental impact studies, it was shown that at concentrations up to 500 ppm, tiamulin did not significantly affect the numbers and motility of Salmonella stanley or E. coli in pond water when the water was examined microscopically after 1 day and 1 week at room temperature.

- Effect On Fish

In preliminary small-scale environmental impact studies, it was shown that no mortality of goldfish was observed at tiamulin concentrations in water less than 160 ppm. At 160 ppm, mortality was observed; surviving fish recovered within 24 hours when exposed to water containing no tiamulin.

(c) Terrestrial ecosystems

- Bioaccumulation factor: It is generally accepted that the octanol/water partition coefficient is an indication of the potential for bioaccumulation. Compounds with partition coefficients greater than 100 have a potential for bioaccumulation while those with partition coefficients, an order of magnitude less, have a low potential for bioaccumulation.

The partition coefficients for tiamulin at two concentrations and at four pH levels have been determined.

Octanol/water partition coefficient for tiamulin:

pH	Concentration (w/v)[1]	Partition Coefficient
4.1	1%	1.05
5.0	1%	1.87
6.0	1%	7.98
7.0	1%	126.25
4.1	0.1%	0.90
5.0	0.1%	3.22
6.0	0.1%	26.73
7.0	0.1%	175.14

[1]Initial concentration in aqueous solution.

At pH levels of 4.1 to 6.0 the partition coefficient is low, thus indicating that tiamulin has a low potential for bioaccumulation. As the pH approaches the pK_{a2}, the base form of tiamulin predominates. Partition coefficients indicate that the base form of tiamulin has a potential for bioaccumulation.

Under field conditions the pH of naturally occurring water will not generally approach the pK_{a2}. It is predicted, therefore, that tiamulin will have a low potential for bioaccumulation.

- Under the specific conditions used to conduct a half-life study, the calculated half-life of tiamulin was 48, 52, 61, and 100 days for sand, sandy loam, clay, and pH 8.0 silt loam soils, respectively.

- Effect On Plants

In preliminary small-scale environmental impact studies, it was shown that tiamulin did not affect the germination or subsequent development of dicotyledonous plants.

- Effect On Soil Microorganisms
  Based on in vitro studies, tiamulin exhibits low activity against gram negative organisms. Tiamulin will, therefore, have no impact on the multitude of gram negative microorganisms, such as Azotobacter, Rhizobium, Nitrosomonas, Nitrobacter, and Thiobacillus, in the soil environment which are responsible for key microbial functions such as nitrification. However, these organisms have not been tested specifically. The conclusion is based on the screening of tiamulin against gram positive and negative pathogenic and intestinal bacteria.

Ultimate Fate of Drug

It would be expected that spilled medicated feed will mix with urine and feces. The final depository for this waste is the soil as there is no economically feasible scheme for treating swine waste to a suitable quality for direct discharge to a water course.

Decomposition of the waste is accomplished by microorganisms under aerobic and anaerobic conditions. This takes place in the soil or prior to ultimate return to the soil if the manure is processed via storage pits, lagoons, oxidation ditches, etc., in which residence time can be extensive (generally greater than two weeks). Although tiamulin does exhibit activity against gram positive organisms, in vitro studies in which tiamulin was screened against gram positive and negative pathogenic and intestinal bacteria show that it has low activity against gram negative organisms. Tiamulin should, therefore, have no impact on the multitude of gram negative microorganisms in the soil environment.

Swine waste is ultimately spread on soil and plowed into the ground at least 8 inches deep at a rate not to exceed 10 tons per acre per year. Assuming one acre of soil to the depth of eight inches weighs about 2.7 million pounds into which 10 tons of swine waste is plowed containing 360 mg of tiamulin spillage, the resulting concentration is approximately 0.00015 mg/kg or 0.15 parts per billion. This is an insignificant concentration and of no environmental concern.

8. ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES

Pollution

- Air
  Use of DENAGARD premixes does not have any effect on air quality, nor will consumption or disposal of the product contribute to air pollution. The vapor pressure of tiamulin is such that even at 45°C the value is 1.5×10^{-7} torr. Tiamulin would not be expected to diffuse into the atmosphere.

- Soil
  Although approximately 1440 kg of tiamulin can be expected to require disposal because of spillage, a soil concentration of less than 0.15 parts per billion would result. This amount of material will not have any effect on the soil microbial population.

- Water
  Water quality should not be affected by the use of the product. Swine waste is not permitted to be discharged to waterways so there will be no direct addition of the product to the water network. Inadvertent pollution of water streams with swine wastes should not result in any significant contamination with tiamulin because of the very low concentration of tiamulin in swine waste.

- Solid and Liquid Wastes
  Use of DENAGARD feed additive has a potential beneficial environmental impact by reducing the amount of Treponema-contaminated swine waste for disposal.

- Toxic Substances
  Tiamulin is a potent antibiotic used in the treatment and control of swine dysentery and for the improvement of growth and feed efficiency. The toxicology is well defined and it has been shown to be safe for use as directed.

  There are no known toxic substances produced by the use, consumption, or disposal of tiamulin.

  The use of tiamulin does not involve substances such as pesticides or heavy metals.

  The occurrence of radiation is not required for any activity associated with tiamulin.

  As noted, the amount of available tiamulin from medicated feed spillage is minimal.

Populations
The action will have no direct effect upon any population. The efficacy of the drug may result in a larger swine population. The human population may be positively affected by an increased availability of pork to the consumer.

Humans
Direct contact of tiamulin with skin or mucuous membranes may cause irritation. The premix label bears the warning: **Avoid contact with the skin. Direct contact with skin or mucous membranes may cause irritation.** However, exposure would occur only during formulation and to a much lesser degree when preparing medicated feed. Such exposure only involves an extremely small segment of the human population during formulation and an extremely small exposure during medicated feed mixing.

Mean levels of total tiamulin residues in tissues are below the established tolerance in less than 1 day of withdrawal. Therefore, there is no potential impact from exposure to unsafe residues in swine tissues.

Plants

In preliminary small-scale environmental impact studies it was shown that tiamulin did not affect the germination or subsequent development of dicotyledonous plants.

Animals

- Exposure to Medicated Feed

  Medicated feed containing tiamulin is given only to swine. These animals generally would be confined in areas from which other animals are excluded. Although exposure of other animals to the medicated feed is possible, it would be very limited. The probability of other animals receiving a significant amount of tiamulin is extremely low.

  Incompatability of monensin and tiamulin has been observed in chickens resulting in weakness, ataxia, reduced feed intake, and death. Liver perfusion studies indicate a decreased rate of monensin elimination in the presence of tiamulin and the resulting toxicity due to the accumulation of monensin. The apparent incompatability extends to other species, including turkeys as reported by Weisman, et al.

  The medicated feed which is spilled by swine in total confinement housing or which is processed via lagoons, storage pits, oxidation ditches, etc., is not physically available to other animals. The only source for potential exposure is that medicated feed deposited in non-confinement housing. The binding potential of tiamulin to soil is high. Therefore, little if any of the spilled material would be available to other animals common to the farm environment. Since the availability of tiamulin medicated feed in the non-confinement situation is also limited, the risk to scavenging birds is considered minimal.

Exposure to Swine Feces Containing Spilled Tiamulin

- Animals

  Animals common to the farm environment do not consume swine feces, thus, there is no direct exposure to the spilled tiamulin contained therein.

- Birds

  The only sources for potential exposure to swine feces are those deposited in non-confinement housing.

  Scavenging fowl and/or wild birds are not recognized to consume feces directly. Birds have an extremely wide range of food preferences, extending from the single-item eaters to the omnivorous species such as crows, gulls, and other scavengers which seem to eat almost anything organic. Based on observations and analyses of gastrointestinal contents, great detail has been given of the food eaten by common wild species; feces were <u>not</u> noted as a food item for any of these.

  Manure collection and storage areas associated with swine operations are not known to attract birds when other sources of food are available. When food is scarce, however, some species have been observed to

pick through freshly deposited feces in search of undi- gested grain, worms, insects, etc. Under these circumstances and with proper access to feces from treated swine, there does exist the opportunity for scavenging birds to pick up and consume spilled drug adsorbed to fecal materials. However, this amount would be minute and the microbial population in fecal material would quickly degrade the drug.

It is acknowledged a slight potential risk to scavenging birds from the "spilled" tiamulin found in feces of treated swine. This risk, however, is viewed as minimal.

Human Values
Tiamulin is a drug that is used exclusively in animal agriculture. It has no current or planned use in human medicine and the consumer will not be in direct contact with tiamulin.

Food Contamination
The quality of the environment in terms of the human values regarding food contamination will not be affected by the projected use of DENAGARD. The product is administered only to swine for the control of swine dysentery or for the improvement of growth and feed efficiency. When used according to the label directions, tiamulin will not become a component of food.

9. USES OF RESOURCES AND ENERGY

The small amount of isopropanol not recovered and the energy used in the drying process are irreversible and irretrievable losses.

Natural Resources
No change in the use and accessibility of natural resources will result from the proposed action.

Energy
There is no direct impact on the energy supply or utilization that stems from the use of the product.

Other
There are no expected effects upon endangered or threatened species nor upon properties listed in or eligible for listing in the National Register of Historic Places.

10. MITIGATION MEASURES

Measures to Avoid or Mitigate Potential Adverse Environmental Effects
The only potential adverse environmental consequence would result from inhalation or contact with the skin. In order to avoid or mitigate these adverse effects, the labels bear the warning: Avoid contact with the skin. Direct contact with skin or mucous membranes may cause irritation.

11. ALTERNATIVES TO PROPOSED ACTION

There are no known reasonable alternatives to the proposed action. Denial of the right to administer this drug to swine would be the most adverse potential effect. Economic benefits to swine producer and consumers can result from use of the drug.

12. LIST OF PREPARERS

Wayne H. Linkenheimer

- Qualifications - Manager of Regulatory Affairs and Quality Assurance, Fermenta Animal Health Company.
- Experience - Twenty-five years of experience in all phases of animal health research and development.
- Professional disciplines - Ph.D., University of Pittsburgh School of Medicine with major emphasis in physiology and pharmacology.

Thomas D. Leafe

- Qualifications - Senior Chemist, Industrial Hygiene, Safety and Environmental Affairs. Fermenta Animal Health Company
- Experience ->Seven years of experience in environmental affairs.
- Professional - B.S. Chemistry, St. Joseph's University, Philadelphia, Pennsylvania.

Joseph P. Marciniszyn

- Qualifications - Group Leader, Animal Metabolism, Department of Safety Assessment. Ricerca Inc.
- Experience - Thirteen years of experience in pharmacology and biochemistry. Five years' experience in environmental fate analysis and animal metabolism.
- Professional - B.S. Biology, Georgetown University; M.S. Chemistry, American University; Ph.D. Biochemistry Marquette University School of Medicine.

13. **CERTIFICATION**

The undersigned applicant/petitioner certifies the information furnished in this Environmental Assessment is true, accurate and complete to the best of his knowledge.

7-11-88
Date

Henry D. Bobe
President
Fermenta Animal Health Company

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14. REFERENCES

CONFIDENTIAL MATERIAL

These references, unless published in the scientific literature, are considered to contain trade secret information or proprietary information of Fermenta Animal Health. This material is the property of Fermenta Animal Health, and must not be disclosed or used except as authorized in writing by Fermenta Animal Health Company.

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