ENVIRONMENTAL ASSESSMENT

1. **DATE:** April 23, 1993

2. **APPLICANT:** RHONE-POULENC, INC.
Feed Additives Division

3. **ADDRESS:** 500 Northridge Road., Suite 620
Atlanta, GA 30350

4. **PROPOSED ACTION:** Approval of product for use in the prevention of coccidiosis in sheep. Production site is located at Hess & Clark, Inc., Ashland, Ohio 44805.

5. **CHEMICAL SUBSTANCES INVOLVED:**

Type A Medicated Article: Deccox Premix, containing 6% Decoquinate (6-Decyloxy-7-ethoxy-4-hydroxy-3-, quinolinecarboxylic acid ethyl ester), CAS # 18507-89-6. The Type A Medicated Article is in powder (granular) form. The Decoquinate is supplied by Rhone-Poulenc, Inc.

6. **INTRODUCTION INTO THE ENVIRONMENT:**

(a) Substances Expected to be Emitted.

Emissions from the production of Deccox at this site may reasonably be expected to be limited to dust from the active ingredient (Decoquinate), the grain carrier, and the flowing agent (silicon dioxide). It is probable that the dust will consist of 30%-70% Decoquinate.

(b) Controls to Limit or Eliminate Emissions.

The facility utilizes a 15 hp Dracco Model No. MB-52 dust collector with 52 Dacron-Polyester filter bags. The collected dust and spent filter bags are then disposed of at the local county landfill.

The facility's Hazardous Waste Generator Identification Number is OHD061020871.

The City of Ashland has issued Wastewater Discharge Permit No. C-412107-01 to Hess & Clark, and routinely monitors the plant's wastewater discharge.

The production process may be expected to produce the following wastes; none of which are regulated under RCRA:

1.) Plastic (probably polyethylene) drum liners, containing trace amounts of Decoquinate (6-Decyloxy-7-ethoxy-4-hydroxy-3-quinolinecarboxylic acid ethyl ester).

2.) Paper bags (from tag ends, approved plant damaged material, approved returned goods materials, etc.) containing trace amounts of Decoquinate.

3.) Dry System Cleanup Wastes (vacuum cleaner sweepings), containing typically 30%-60% Decoquinate, 0%-5% paper (from switch-over taping bag-closure operations, with the balance being grain carrier.

4.) Small Amounts of Rejected Material, (i.e., rejected returned goods, rejected plant damaged materials, etc.) containing the labeled limits on specification.

5.) Raw Material Shipping Containers, and

6.) Dust Collector Cleanout, containing typically 30% to 70% Decoquinate, with the balance being carriers.

Empty raw material shipping containers, plastic and paper bags, rejected materials, and system cleanout wastes are either recycled or destroyed and sent to the Ashland County Landfill, as appropriate.

Dust collector cleanouts are accumulated in fiber drums and are sent to the Ashland County Landfill.

Since Deccox Premix will be produced in a dedicated system, routine cleaning of the system will therefore, not be required.

(c) Federal, State, and Local Emission Regulations and Laws

Federal Regulations applicable to Hess & Clark's operations can be found in 29 CFR §1910.1000, §1910.1200, and §1910.1450; 40 CFR §261, §262, §302, §372, and §439.40; and 49 CFR §172. Parts of the Ohio Administrative Guide, Sections 3745-17-08, 3745-51, 3745-52, 3745-100, 4121:1-5-17, 4121:1-5-18; 4121-1-5-991 and Parts 1 and 20 of §3750, are applicable to firms producing products of this nature. Ashland Ordinance 921.10(c) is the only local ordinance that might be applicable to production of Deccox in this facility.

In order to assure worker safety and compliance with the above cited OSHA regulations, the facility provides and requires workers to use some or all of the following safety equipment when working in the Deccox production areas: a.) approved 3-M air line respirators with soft cap, full face shield and shroud or approved cartridge-type respirator; b.) safety goggles; c.) head and facial hair coverings; d.) Tyvek disposable coveralls; e.) Latex gloves and plastic disposable arm covers; and f.) disposable plastic shoe covers.

In compliance with the Community Right-to-Know Laws (Title III of the Superfund Amendments and Reauthorization Act), the facility has available to its employees, Material Safety Data Sheets on the raw materials and finished products and trains all employees in the location and understanding of these MSDS's. Additional education, safety and refresher meetings are conducted on a routine basis.

(d) **Certification**

We hereby certify that the facility is in compliance with all known federal, state, and local regulations pertaining to worker safety, environmental protection, or the production of Type A feed premixes.

(e) **Effects of the Approval Upon Compliance with Current Emission Requirements; Estimated Yearly Market Volume.**

The approval of the supplemental NADA is not expected to have any effects upon compliance with current emission requirements. Any hazardous waste material generated as a result of this production will be properly disposed of by Laidlaw Environmental Services (T.S.), Inc., Greenbrier, TN.

The estimated yearly market volume is 150,000 pounds of active ingredient (Decoquinate).

7-11. NOT APPLICABLE TO THIS ENVIRONMENTAL ASSESSMENT

12. LIST OF PREPARERS:

This environmental assessment was prepared by Jeff Moorman.

13. CERTIFICATION:

The undersigned certifies that the information is true, accurate, and complete to the best knowledge of the firm.

Date May 10, 1997

Signature _____

Title: Director - Product Development and Regulatory Affairs

14. REFERENCES:

A. Code of Federal Regulations

B. Merck Index, Eleventh Edition

C. Ohio Administrative Guide

Environmental Impact Assessment for the Use of Decoquinate to Prevent Coccidiosis in Sheep

May 1989

Rev September 1989

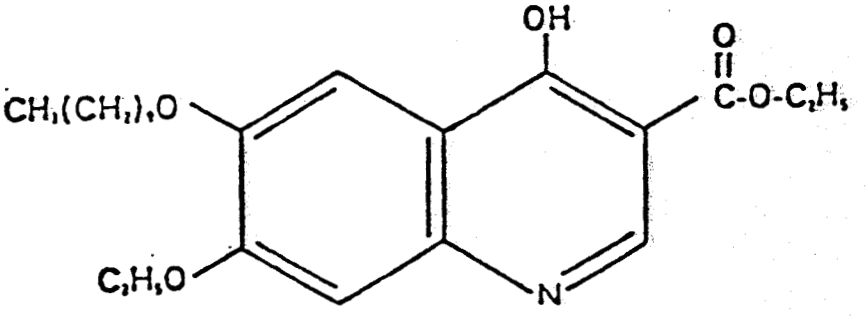
Description of Use

It is proposed that decoquinate be fed continuously for 120 days at 25g/ton (0.5 mg/kg live weight) to young sheep maintained in feed-lots for the prevention of coccidiosis caused by E. ovina, E. crandallis, E. ovinoidalis, (E. ninakohlyakimovae), E. parva and E. intricata in sheep.

The control of coccidiosis in sheep, especially lambs, is important since infective outbreaks are characterized by watery diarrhea, weight loss, unthriftyness and increases in mortality. Outbreaks of the clinical manifestations of the disease are usually observed in young, growing sheep because of stress and somewhat unsanitary and crowded conditions. Older sheep can be reservoirs of the coccidia oocysts and shed oocysts in their feces. Practically all young sheep can acquire coccidia infections.

Chemical Identity and Properties

Decoquinate (ethyl-6-decyloxy-7-ethoxy-4-hydroxy-3-quinolinecarboxylate) has the molecular formula $C_{24}H_{35}NO_4$ and a molecular weight of 417.5. It has a melting point of 242-245°C. The CAS number is [18507-89-6] and has the structural formula:



Solubility:

Water- practically insoluble; less than 1 part in 10^5. At pH 4-10 the solubility is 0.122-0.204 ug/mL; in distilled water the solubility was 0.25 ug/mL.

Methyl alcohol- 0.1%

Ethyl alcohol, acetone, dimethylformamide, toluene - < 0.1%

Chloroform- 0.3%

0.1 N NaOH in methyl alcohol- 1.4%

Stability: Decoquinate is stable for long periods when stored in a cool, dry place.

Light absorption: A 6 x 10^{-4} % solution in acid ethanol (10 mL 0.1 N HCl in 100 mL alcohol exhibits UV maximum absorption at 265 nm. The $E^{1\%}$ at 265 nm in acidified alcohol lies within the range of 988 and 1024.

Introduction into the Environment Through Proposed Use

The use of decoquinate, fed at 25g/ton (approximately o.5 mg decoquinate/Kg live weight) for 120 days to young sheep for the prevention of coccidiosis, under feed-lot conditions, is necessary to prevent economic losses from increased mortality, poor growth and unthriftyness.

Assumptions

The following assumptions were used in the estimation of the environmental impact of the proposed use of decoquinate in sheep:

1- The weight of the young sheep was 20 Kg or 44 lbs.

2- The amount of medicated feed consumed/day/sheep necessary to provide the 0.5 mg decoquinate/Kg live weight is 400 g.

3- Weight of solid waste produced/sheep/day is approximately 200 g.

4- Weight of liquid waste produced/sheep/day is approximately 800g.

5- Decoquinate is fed for 120 consecutive days; it will take another 28 days for all the decoquinate to be excreted from the tissue. It is assumed that 90% of the decoquinate fed will be excreted.

6- Twenty five lbs of bedding will be used per animal.

7- A herd of 250 young sheep will be used as the model herd.

8- The bedding and waste products will be removed after 148 days and disposed of by plowing into soil at the rate of 5 tons /acre at a depth of 6".

9- Decoquinate would not undergo degradation prior to soil disposal.

Concentration of Decoquinate in Wastes

Total Amount of Decoquinate Excreted

250 sheep x 500ug decoquinate/20 Kg sheep/day x 120 days x 0.90 (amount excreted) = 13,500,000 ug decoquinate excreted.

Waste Produced

250 sheep x 1000g waste produced/day x 1 Kg/1000g x 148 days (120 days feeding + 28 additional days for excretion x 2.2 lbs/Kg = 81,400 lbs

250 sheep x 25lbs bedding/sheep = 6,259 lbs

Total Waste Produced = 87,650 lbs

= 43.825 tons

Concentration of Decoquinate in the Waste

13,500,000ug decoquinate / 87,650 lbs waste x 454 g/lb = 13,500,000 ug decoquinate / 39,793,100g waste = 0.339 ug decoquinate / g waste.

Concentration of Decoquinate in Soil After Plow-in Disposal

13,500,000 ug decoquinate /

43.865 tons/5 acres x 43,560 ft^2/acre x 144 in^2/ft^2 x 16.4 cm^3/in^3 x 1.5 g/cm^3 = 13.5 x 10^6/8.12 x 10^9 = 1.66 x 10^{-3} ug decoquinate/g soil = 1.66 ppb decoquinate in soil

Degradation of Decoquinate in Soil

Decoquinate is very stable in the soil, in manure and to bacterial action, as exemplified by its stability in rumen fluid. Estimates of degradation on cow manure after storage for 6 to 8 months ranged from 8 to 60%. Degradation in rumen fluid was insignificant also. Decoquinate is quite stable to bacterial degradation; hence, slow degradation in soil is expected.

With the data available, any calculation of the half-life of decoquinate in soil is relatively impossible. Assuming, for the purpose of this assessment, that decoquinate decomposes at the rate of 20% of the original concentration within 6 months, the half-life would be 18 months. Although the degradation of decoquinate in the soil is slow, the projected levels in the soil are so low, 1.66 ppb, that it would be impossible to detect. If the level of disposal was raised to 20 tons of manure-bedding waste/acre, the concentration in the soil would be only 6.64 ppb, a level too low to be measured.

Potential for Leach or Run-Off

Decoquinate is bound tightly to both soil and manure and/or their mixture. It is not expected to undergo any significant leach or mobility in the soil. Percolation studies indicated that decoquinate was tightly bound and had little or no probability of any significant movement.

With such a low probability of leach and mobility, there is little justification to calculate leach of decoquinate into aquatic systems.

Bioaccumulation

There are no data available on bioaccumulation or biomagnification. The low solubility and binding of decoquinate to soil components minimize movement. Tissue residue studies using ^{14}C-labeled decoquinate indicated that decoquinate residues were greater in liver, kidney and fat than those found in muscle, 0.3 to 1.0 ppm versus 0.1 to 0.3 ppm. This pattern of residue distribution did not indicate any highly preferential lipid solubility; hence there was a minimal potential for either bioaccumulation of biomagnification.

Effects Upon Microorganisms

In general, decoquinate is inactive against bacteria, yeasts and fungi. It was inactive against*Aspergillus fumigatus*, *Candida albicans*, *Erysipelothrix insidiosa*, *E. coli*, *Pasteurella multicida*, *Salmonella* spp., *Staphylococcus aureus*, *Streptococcus algalactiae*. The only reported effects were against the blue green algae.

Phytotoxicity

Decoquinate was reported not to be phytotoxic at a level of 8 lbs of active ingredient/ acre. If on assumes a one-inch depth to a seed bed, the following concentrations would be present:

8 lbs decoquinate x 454g/lb x 1000 mg/g x 1000 ug/mg /

1 acre x 43,560 ft^2/acre x 144 in^2 x 1 inch depth x 16.4 cm^3/in^3 x 1.5g/cm^3(soil density) = 3.63 x 10^9 ug decoquinate/ 1.54 x 10^8/g soil = 23.6 ug decoquinate/g soil or 23.6 ppm. For a seed-bed depth 2", the concentration would be 11.79 ppm; for a 4" seed-bed depth, the concentration would be 5.58 ppm; for a 6" seed-bed depth, the concentration would be 3.93 ppm.

For the 6"-depth, the non-phytotoxic concentration is over 2000 times greater than the ~~than the~~ level calculated to result from the plow-in disposal.

No toxic effects were reported for the following plants: wild radish, corn mayweed, wild oats, meadow foxtail, lamb quarters, pale smartweed, common duckweed or annual blue grass. There were no data found that indicated that extrapolation could be made to crops of economic importance such as corn, soybeans, sorghum, alfalfa, tomatoes, peppers and lettuce.

Effects on Representative Non-Target Organisms

Animal	Dose and Commentary
Beagle	no effect level, 13-week daily dose > 15 mg/Kg but < 62.5 mg/Kg
Rat	12-day study- 2g/kg/day- no toxicity
Rat	single oral dose-minimum lethal dose >5mg/Kg
Rat	26-week feeding, 200, 2,000, 20,000 ppm 2,000 ppm no effect dose
Chicken	5mg/Kg no toxic effects-2 weeks post dosing
Chicken	5gm/Kg, minimum toxic dose > 5 gm/Kg
Chicken	0.004% diet-no effects up to 22 weeks no effects on onset of egg laying or production

Chicken	0.32% in feed- no histopatholgy up to 180 days
Pheasants, pigeons partridge	acute LD_{50} > 5.0 gm/Kg
Earthworms Springtails Sheep blow worms	inactive against
Aquatic Species	no data available

Overall Assessment

The use of decoquinate in young sheep for the prevention of coccidiosis, under feed-lot conditions, should impose no detrimental effects upon the environment. Although a 250-animal model was used in the assessment, the impact upon the environment for a 5000-animal model would not change the assessment. As was noted, soil disposal of the drug-containing waste-bedding mixture at a rate of 20 tons/acre, rather than at the 5 tons/acre mode, would not raise the soil levels above 6.64 ppb. At this level there would be no environmental effects. The 5000-animal model would only require a larger disposal area. Soil disposal of the waste-bedding mixture should not exceed 20 tons/ acre because of the detrimental effects that level of manure could have on the soil disposal area. Because of the stability of decoquinate in the soil, the area assigned for soil disposal should be used relatively infrequently to prevent the possibility of decoquinate build-up.

The test plant used in the phytotoxicity studies were not plants of economic value; the plants were weeds and are probably far more hardy than plants of economic importance. However, the large differences between the decoquinate soil concentrations

calculated for disposal and the levels that could give some phytotoxic effects are so great, at least a factor of 2000, constitutes a safety factor.

Other than the caution concerning the prudent use of the disposal acreage, the use of decoquinate for the prevention of coccidiosis in feed-lot sheep should have no impact upon the environment.

Preparation of the Assessment

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

References

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4-Safety, Efficacy and Toxicology Summaries, EIAR, 1975.

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6-The Merck Index, Tenth Edition, 1982. Merck & Co., Inc. Rahway, NJ.