

ENVIRONMENTAL IMPACT ASSESSMENT REPORT
SUBTHERAPEUTIC USE OF ANTIBIOTICS FOR ANIMAL FEEDS
(Reference 21 CFR Part 500, FR Vol. 62, No. 103, May 27, 1977)

Sponsor: A. L. Laboratories, Inc.
452 Hudson Terrace
Englewood Cliffs, New Jersey 07632

Sponsor No.: 46573

Drug: Bacitracin Methylene Disalicylate

NADA: Bacitracin Methylene Disalicylate Soluble, 65-280;
Bacitracin Methylene Disalicylate Feed Grade, 46-592

I. ~~Introduction into the Environment~~

- a) Total quantity of the drug produced for all uses, portion used subtherapeutically in animal feeds, relative magnitude of other uses, uses in humans.

Total quantity of bacitracin methylene disalicylate produced annually for all uses is about 135,000 kg. Of this amount, 125,000 kg are used subtherapeutically in animal feeds and 10,000 kg are used therapeutically in animal drinking water.

None is used in humans.

- b) Pollutants generated and resources consumed by the manufacture of the drug, premix, including energy uses.

Any pollutants generated are negligible and controlled. In the manufacture of the product for subtherapeutic purposes in feed, the total fermenter contents goes by closed system into a spray drier. The water vapors, odors and gases are retained in a closed system and passed through an incinerator at 1500°F with only carbon dioxide and water vapor returned to the atmosphere. The manufacture of Bacitracin MD involves a fermentation using harmless nutrients and a non-pathogenic organism. Airborne products involve only carbon dioxide enriched air. (See attachment 1)

In the manufacture of the soluble bacitracin methylene disalicylate, the air-borne products involve only carbon dioxide enriched air having a slight, non-persistent odor from the fermentation step and moisture laden air from the spray drier, with negligible amounts of product dust.

Solid products involve essentially only the water-wet materials resulting from the filtration of the fermented broth. Each batch will contain a total of about 21,000 lbs of the filter aids, mycelium and insolubles from the broth nutrients. This solid material is essentially biodegradable or harmless inert material and is disposed of via sanitary land fill.

The liquid waste product is generated at one point only - that is where the active completed component is filtered off in insoluble form, and the aqueous liquor discarded to municipal sewage system for handling in the treatment facility. About 20,000 gallons are discharged per batch containing minor (1-2%) amounts of non-toxic salts and biodegradable organics with no basic problems created that can have a measureable lasting or cumulative effect on the environment. (See attachment 2)

No objections have been raised by any agencies, organizations or individuals to the current operations. (See attachments 3, 4 and 5)

Resources consumed in the manufacture of feed grade bacitracin methylene disalicylate (Fortracin Concentrate TSD):

<u>Resource</u>	<u>Per standard kg.</u>
City Water	20.67 gal.
Steam condensate	8.33 "
Soya flour	21.67 pounds
Magnesium sulfate	4.33 "
Degerminated cornmeal	3.33 "
Calcium carbonate	0.33 "
Hodag M-8	0.94 "
Methylene disalicylic acid	1.33 "
Sulfuric acid (50%)	4.84 "
Sequesterene NA2	.03 "
Sodium hydroxide (50%)	.42 "
Cabosil	.03 "

Resources consumed in the manufacture of the bacitracin methylene disalicylate soluble (Fortracin Soluble Concentrate):

Resource	Per standard kg.
City water	31.00 gal.
Steam condensate	12.50 "
Soya flour	32.50 pounds
Magnesium sulfate	6.50 "
Degerminated corn meal	5.00 "
Calcium carbonate	0.50 "
Hodag M-8	1.41 "
Hydrochloric acid 20° Baume	9.00 "
Methylene disalicylic acid	2.50 "
Sequesterene NA2	0.05 "
Sodium hydroxide (50%)	4.50 "
Sodium hydrosulfite	0.05 "
Perlite filter aid	4.00 "
Hyflo Super Cel	10.00 "
Solka-floc	1.00 "
Sodium bicarbonate	0.31 "
Sodium hydroxide USP pellets	0.25 "
De-ionized water	1.25 "

In the manufacture of bacitracin methylene disalicylate soluble concentrate, 1,783,430 BTU are used for each standard kg. For the feed grade bacitracin methylene disalicylate TSD 3,690,000 BTU are used in production of each standard kg.

A representative formula for a 1200 pound batch of soluble premix is:

249 lbs. Soluble Fortracin Concentrate - 241 grams* of Bacitracin (Master Standard) per pound
120 lbs. Bicarbonate of Soda USP
300 lbs. Fruit Granulated Sugar (X fine granulated sugar)
300 lbs. Cerelose Anhydrous Dextrose 2421
230-1/2 lbs. Cerelose Anhydrous Dextrose 2401
1/2 lb. Petro Ag. Special Ultra Fines Anti-caking Agent

*The Soluble Fortracin *Concentrate* received is un-standardized and, therefore, is not in every case 241 grams bacitracin per pound. To the extent that it varies from this figure, minor adjustments are made with the ingredient weights shown on the representative batch formula to obtain a standardized product of 50 grams bacitracin per pound.

Routes through which the drug may pass into the environment, amounts passing through various routes, during manufactures, preparation of premixes, excretion by target animals..

Any dust generated in blending of the premix is subject to pickup by a dust collector and is considered only a minor source going into the environment.

The antibiotic passes through the animal in the excreta. Its disappearance from the faeces is surprisingly rapid.

The following example shows this with broiler chickens fed continuously a mash feed containing 500 g bacitracin MD per ton of feed:

<u>Sample</u>	<u>Bacitracin found* (ppm)</u>
Fresh faeces	6.17
Same held 24 hours RT	5.00
Same held 72 hours RT	4.89
Same held 7 days	1.30
Same held 14 days	0.14
Same held 21 days	0.14

*All values are on a dry matter basis. The experiment was done by Dr. T. Chang, Michigan State University, E. Lansing.

Inactivation of zinc bacitracin in faeces from laying hens was studied by S. Thomassen and K. Vaaji, A/S Apothekernes Laboratorium, Oslo, Norway (1976). In their first experiment, zinc bacitracin was mixed with faeces from laying hens to a final concentration of 10 and 100 ppm. The faeces was stored in plastic bags at 15°C for 15 days and assayed at regular intervals. A rapid inactivation of the antibiotic was observed. The half-life of the antibiotic was estimated to 6 days..

In a second experiment, the hens were fed feeds with 100 ppm zinc bacitracin. The faeces were stored for 11 days in open glass jars. The-half-life was estimated at 4 days.

The objective of a third experiment was to study the inactivation of zinc bacitracin in faeces from laying hens after storage under natural conditions in the dung in the hen house. This experiment was in a commercial layer flock of 15,000 birds, half was fed 100 ppm zinc bacitracin in their diet, the other half was fed the same diet without antibiotic. The birds were caged on a mesh floor and the faeces was deposited in a pit under the floor. Sampling was carried out in May and August, 1975. The half-life estimates were 7 and 2 days for the May and August samplings.

From the cited examples, it appears that Bacitracin MD and zinc bacitracin are biologically inactivated. rapidly in faeces with rate of disappearance being affected by temperature, moisture and pH.

II. Fate in the environment

- a) Mobility of the antibiotic in the environment measured by leaching potentials, vaporization, absorption in soils.

This has not been done, but the physical conditions of the media would cause rapid destruction.

- b) Stability and persistence of the antibiotic in those environments where it is determined that it will be introduced or those environments to which it is subsequently transported.

The available data indicates that the antibiotic is not stable in the faeces of animals; and consequently, would not reach or persist in the environment. (See I.c.)

- c) Potential for the antibiotic to be accumulated or bioconcentrated by plants, animals and micro-organisms measured by such factors as lipid/water partitioning or studies with animals.

This has not been investigated. The cited work shows that the half-life of the antibiotic is short and that it is not absorbed by target animals.

The antibiotic is not absorbed from the intestinal tract of the animal as shown by the fact that no detectable bacitracin has been found in the tissues or eggs when the feed of chickens, turkeys, and laying hens were consuming feeds containing as much as 1000 grams antibiotic per ton of feed on the day that they were sacrificed for tissue harvest. No detectable bacitracin residues have been found in tissues of cattle or swine when they had been consuming feeds containing 500 g antibiotic per ton. Reference is made to the bacitracin MD submission of January 15, 1971, pp 440-697 in NADA 46-592.

III. Environmental Effects

- a) Effects of antibiotic on organisms important to key ecological processes, such as fresh water algae, nitrogen-fixing bacteria, nitrifying bacteria, soil fungi, and bacteria responsible for nutrient mineralization.

This has not been investigated. The bacitracins are effective

against gram-positive organisms, not gram-negative organisms. Most nitrogen-fixing bacteria, nitrifying bacteria, etc., are gram-negative bacteria. For example: the Azotobacter is an aerobic, free-living nitrogen fixer; Rhizobium are Aerobic symbiotic nitrogen fixers; Nitrosomonas, nitrobacter, Thiobacillus, Pseudomonas, and acetobacter are aerobic organisms that oxidize inorganic and/or organic compounds.

The following table was taken from Microbiology, 2nd ed., Davies, et al, Harper Row, Hagerstown, MD:

GRAM-NEGATIVE BACTERIA, EXCLUDING PHOTOSYNTHETIC FORMS						
Cell Shape	Motility	Other distinguishing characteristics		Genera	Families	
Cocci	Permanently Immotile	Aerobic		Neisseria	Neisseriaceae	
		Anaerobic		Veillonella		
				Brucella	Brucellaceae	
				Pasteurella		
				Hemophilus		
				Bordetella		
Straight rods	Motile with peritrichous flagella, and related immotile forms	Facultative anaerobic	Mixed acid fermentation of sugars	Escherichia	Enterobacteriaceae	
			Butylene glycol fermentation of sugars	Erwinia		
				Shigella		
				Salmonella		
				Proteus		
				Enterobacter		
				Serratia		
		Aerobic	Free-living nitrogen fixers	Azotobacter	Azotobacteriaceae	
			Symbiotic nitrogen fixers	Rhizobium	Rhizobiaceae	
	Motile with polar flagella	Aerobic	Oxidize inorganic compounds	Nitrosomonas	Nitrosomonadaceae	
			Oxidize organic compounds	Nitrobacter		
				Thiobacillus	Thiobacillaceae	
				Pseudomonas	Pseudomonadaceae	
				Acetobacter	Acetobacteraceae	
		Facultative anaerobic		Photobacterium		
				Zymomonas		
				Aeromonas		
Curved rods	Motile with polar flagella	Comma-shaped	Spiral	Aerobic	Vibrio	Spirillaceae
				Anaerobic	Desulfovibrio	
					Spirillum	

- b) Effects on fish, mammals and other vertebrates that are important to man as food, or food for human-food producing animals or organisms that are of aesthetic interest to man, etc.

This has not been investigated. The bacitracins are non-toxic drugs that are used in animals consumed as food by humans, and the animal by-products are consumed by other animals. The antibiotic is not absorbed from the intestinal tract, thus it is concluded that there would be no effect.

- c) Indirect effects on populations or organisms and communities that might arise from the subtherapeutic use of the drug.

The requirements have been satisfied for 21 CFR 558.15. The accumulated data showed that the Animal-Human Health criteria have been met for safe use of low levels of bacitracin(s) in animal feeds. Dr. Gerald B. Guest's letter of September 27, 1976 concludes that "the review of required data for bacitracin is hereby concluded.. Results indicated that the use of low levels of bacitracin in animal feeds satisfied the animal and human safety criteria for safety as specified by the Antibiotics in Animal Feeds Task Force."

In these investigations, it was shown that the low level feeding of bacitracin to swine and chickens did not affect the salmonella or E. coli populations or mediate a change in resistance or cross resistance to antibiotics used in human medicine. Reports are on record in Bureau of Veterinary Medicine.

PENICK

ATTACHMENT 1

1050 Wall Street West, Lyndhurst, New Jersey 07071 • Telephone: (201) 935-6600 • Telex: 133525

a Unit of CPC International Inc.

Address Reply To:
S.B. PENICK & COMPANY
640 New York Avenue
Lyndhurst, N.J. 07071
Phone: (201) 438-6000

July 12, 1977

ENVIRONMENTAL IMPACT ANALYSIS
FORTRACIN CONCENTRATE TSD 46-592

Introduction

This Environmental Impact Analysis is being submitted in response to a request published in the Federal Register of Friday, May 27, 1977 (pp. 27264-27266). The above product has been produced by S. B. Penick and Company for over 10 years and in its present spray-dried version for the last 4 to 5 years.

Name of Applicant

A. L. Laboratories, Inc.
452 Hudson Terrace
Englewood Cliffs, New Jersey 07632

Custom Manufacturer:

S. B. Penick & Company, a Unit of CPC International Inc.
158 Mt., Olivet Avenue
Newark, New Jersey 07114--Manufacturing Plant

1. Manufacturing Procedure

The manufacture of Fortracin Concentrate TSD 46-592 involves a fermentation using harmless nutrients and a non-pathogenic organism, followed by the addition of an organic complexing agent and subsequent spray drying; blending, and packaging to obtain the final bulk product.

All steps are carried out at the Newark, New Jersey Plant of S. B. Penick & Company.

Continued .

2. Probable Impact on the Environment

No significant impact on the *environment* is believed created, for the following reasons:

- a) There are essentially no by-products. No filtration cakes, nor waste mother liquors are created for disposal.
- b) The exhaust air from the spray dryer is incinerated at approximately 1500 F, thereby eliminating all possible discharges of odors and dust from this process.
- c) No solvents are utilized in this process.

3. Probable Adverse Environmental Effects Which Cannot be Avoided

No adverse environmental effects are being created.

4. Alternatives to the Current Method of Operation

No practical alternatives to the current method of operation are known, which would offer less impact on the environment.

5. Relationship-Local Short-Term Uses of Environment; and the Maintenance and Enhancement of Long-Term Productivity

No measurable lasting or cumulative effect on the environment is foreseen, due to the current method of operation.

6. Irreversible or Irrecoverable Commitments of Resources Due to Current Operation

Current operations cause no irreversible or irretrievable commitment of resources.

7. Objections Raised by Other Agencies, Organizations or Individuals

No objections to current operations by any agencies, organizations or individuals are known to have been raised, or to be in existence.

8. Action Schedule

Since no change is contemplated over the current, long-standing method of operation, no schedule problems are involved.

Continued .

9. Benefits vs Risk to the Environment

The negligible risks to the environment due to the operations involved are far overshadowed by the benefits to mankind created, by making a valuable food additive and growth stimulant available to the food producing industry, at a time when global food requirements are drastically inadequate.



D. Albright, Plant Manager
Newark Plant

DA:bg

S. B. PENICK & COMPANY • 100 CHURCH STREET, NEW YORK, N. Y. 10007 • Cortlandt 7-1970
a Unit of **EPC** International Inc.

Address Reply to:
158 Mt. Olivet Ave.
Newark, N. J. 07114
Phone: (201) 243-4662

January 12, 1976

ENVIRONMENTAL IMPACT ANALYSIS
SOLUBLE FORTRACIN CONC.65-280

Introduction

This Environmental Impact Analysis is being submitted as requested by Robert A. Baldwin, of the Department of Health, Education & Welfare, of FDA in a letter dated September 4, 1975, for record purposes for the above product, which has been produced by S.B. Penick & Company for over 10 years.

Name of Applicant

A.L. Laboratories, Inc.
452 Hudson Terrace
Englewood Cliffs, New Jersey 07632

Custom Manufacturer:

S.B. Penick & Company, a Unit of CPC International Inc.
158 Mt. Olivet Avenue
Newark, New Jersey 07114--Manufacturing Plant
and
540 New York Avenue
Lyndhurst, New Jersey 07071--Manufacturing Plant (Spray Drying Only)

1. Manufacturing Procedure

The manufacture of Soluble Fortracin Conc.65-280 involves a fermentation using harmless nutrients and a non-pathogenic organism, followed by isolation by filtration of a solid active component, with subsequent spray drying of the solubilized component; blending, and packaging to obtain the final bulk product.

All steps are carried out at the Newark, New Jersey Plant of S.B. Penick & Company, except for the spray drying, which is done at their Lyndhurst, New Jersey Plant.

Continued.....

Environmental Impact Analysis

Page 2

January 12, 1976

2. Probable Impact on the Environment

No significant impact on, the environment is believed created, for the following reasons:

- a) The quantity being produced per year is small. Typical annual production might be a total of 25 batches, giving a total annual production of approximately 7,500 standard kilograms.
- b) Airborne by-products involve only (1) Carbon dioxide enriched air having only a slight, non-persistent odor from the fermentation step, and (2) Moisture laden air from the spray dryer, which might have also 10-12 Kg/batch of product dust (an animal feed enrichment component, and basically harmless).
- c) Solid by-products involve essentially only the water-wet filter cake resulting from the filtration of the fermented broth. Each batch will contain about 13,000 lbs. of filter aids; 4,000 to 6,000 lbs. of mycelium; and 4,000 to 6,000 lbs. of insolubles from the broth nutrients. This solid material, essentially biodegradable or harmless inert materials, is disposed of via sanitary landfill at the Kearny Municipal Facility
- d) Liquid waste by-product is generated at essentially one point only--that where the active complexed component is filtered off **in** insoluble form, and the aqueous mother liquor discarded to the Newark Municipal Sewage System, for handling in the treatment facility of the Passaic Valley Sewerage Commissioners. About 20,000 gallons are discharged per batch. With minor (1%-2%) amounts of nontoxic salts, and also of biodegradable organics present, **no** basic problems with respect to the environment are created.
- e) No solvents are utilized in this process.

3. Probable Adverse Environmental Effects Which Cannot be Avoided

No adverse environmental effects are being created.

4. Alternatives to the Current Method of Operation

No practical alternatives to the current method of operation are known.

5. Relationship-Local Short-Term Uses of Environment; and the Maintenance and Enhancement of Long-Term Productivity

No measurable lasting or cumulative effect on the environment is foreseen, due to the current method of operation.

Continued

6. Irreversible or Irretrievable Commitments of Resources Due To Current Operation

Current operations cause no irreversible or irretrievable commitment of resources.

7. Objections Raised by Other Agencies, Organizations or Individuals

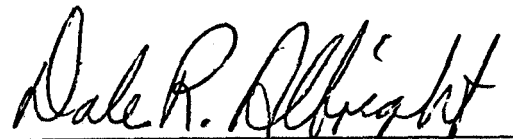
No objections to current operations by any agencies, organizations or individuals are known to have been raised, or to be in existence.

8. Action Schedule

Since no change is contemplated over the current, long-standing method of operation, no schedule problems are involved.

9. Benefits vs Risk to the Environment

The negligible risks to the environment due to the operations involved are far overshadowed by the benefits to mankind created, by making a valuable food additive and growth stimulant available to the food producing industry, at a time when global food requirements are drastically inadequate.



D. Albright, Plan Manager
Ne ark Plant

NEW JERSEY STATE DEPARTMENT



OF ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT TO CONSTRUCT, INSTALL OR ALTER CONTROL APPARATUS OR EQUIPMENT

TO: New Jersey State Department of Environmental Protection
Bureau of Air Pollution Control
P. O. Box 1390
Trenton, New Jersey 08625

Date April 10, 1972

Use instructions, Air-D13

Sec. A	1. Full Business Name <u>S.R.Penick, a Unit of GPC International</u> 2. Address of equipment and/or control apparatus: <u>158</u> <u>Mt. Olivet Ave.,</u> <u>Newark</u> <u>Essex</u> No. Street Municipality County 3. Location on premises (Bldg., Dept., area etc.) <u>Bldg. 27</u> 4. Nature of Business <u>Fine Chemicals Manufacturing</u> SIC No. <u>2833</u>																								
Sec. B	1. <input checked="" type="checkbox"/> New process equipment and new air pollution control apparatus <input type="checkbox"/> New air pollution control apparatus on existing process equipment <input type="checkbox"/> New process equipment with no control apparatus <input type="checkbox"/> Other: _____ 2. Prior permit numbers covering this installation. Specify. <u>None</u> 3. Estimated starting date <u>4-15-72</u> Estimated completion <u>12-15-72</u>																								
Sec. C	1. Description of operation <u>Spray drying operation for the production of animal feed grade antibiotics.</u> 2. Identify process equipment <u>DeLaval Spray Dryer and Flex-Kleen bag product collector</u> 3. Raw materials (names) <u>Aqueous slurries/solutions of animal feed grade antibiotics</u> Total pounds per hour <u>6,200 of sol'n.</u> Total pounds per batch _____ 4. Operating procedure: <input checked="" type="checkbox"/> Continuous: <u>24</u> hrs. per day <u>20</u> days per <input type="checkbox"/> week <input checked="" type="checkbox"/> month <input type="checkbox"/> Batch: _____ hrs. per batch _____ Batches per <input type="checkbox"/> day <input type="checkbox"/> week																								
Sec. D	Physical and chemical nature of air contaminants which must evolve from operation and be emitted into the open air: <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width:50%;">AIR CONTAMINANTS</th> <th colspan="2">AMOUNTS OF CONTAMINANTS</th> </tr> <tr> <th style="width:25%;">With Control Apparatus</th> <th style="width:25%;">Without Control Apparatus</th> </tr> </thead> <tbody> <tr> <td>Feed Grade Antibiotics</td> <td>Less than 0.1 lb/hr</td> <td>16 lbs/Hr.</td> </tr> <tr> <td></td> <td>of mineral ash,</td> <td>Feed grade antibiotic</td> </tr> <tr> <td></td> <td>chiefly Calcium</td> <td>dust</td> </tr> <tr> <td></td> <td>& Magnesium</td> <td></td> </tr> <tr> <td></td> <td>Sulfates</td> <td></td> </tr> <tr> <td colspan="3">Operation will not add odors to the atmosphere detectable beyond property limits.</td> </tr> </tbody> </table>		AIR CONTAMINANTS	AMOUNTS OF CONTAMINANTS		With Control Apparatus	Without Control Apparatus	Feed Grade Antibiotics	Less than 0.1 lb/hr	16 lbs/Hr.		of mineral ash,	Feed grade antibiotic		chiefly Calcium	dust		& Magnesium			Sulfates		Operation will not add odors to the atmosphere detectable beyond property limits.		
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	& Magnesium																								
	Sulfates																								
Operation will not add odors to the atmosphere detectable beyond property limits.																									

Sec. E

1. Describe air pollution control apparatus The air from the Spray Dryer is first passed through a Flex-Kleen bag-type dust collector; then through a Cor-Pak fume incinerator for incineration at 1200°F for 0.5 seconds, followed by passage through heat exchangers to the stack, for discharge to the atmosphere.
2. Efficiency of control apparatus: 99.9 % min. for the dust collector
3. Height of discharge above ground 50 ft.
4. Distance from discharge to nearest property line 160 ft.
5. Volume of gas discharged into open air 11,000 cu. ft. per min. at stack conditions
6. Exit linear velocity at point of discharge 62 ft. per minute at stack conditions
7. Temperature at point of discharge 360 °F
8. Will emissions comply with existing local requirements? Yes
9. Initial cost of control apparatus \$ 285,000
10. Estimated annual operating cost \$ 94,000

This application is submitted in accordance with the provisions of N.J.S.A. 26:2C-9.2, and to the best of my knowledge and belief is true and correct.


Signature - all copies

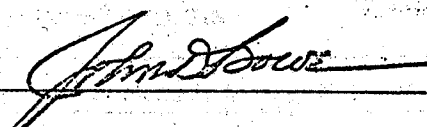
S.B. Penick & Co.
540 New York Ave.
Mailing Address
Lyndhurst, N.J. 07071
Zip Code

M. Michiels
Name (Print or type)
Chief Engineer
Title
201-438-6000
Telephone No.

DO NOT WRITE BELOW

PERMIT TO CONSTRUCT, INSTALL OR ALTER CONTROL APPARATUS OR EQUIPMENT

Application for permission to construct, install or alter the equipment and/or control apparatus as set forth above is APPROVED.

Date 4-28-72 Approved by: 

PERMIT NO. P-7469 Supervisor, Permits & Certificates

Submit original and three (3) copies



NEW JERSEY STATE DEPARTMENT OF ENVIRONMENTAL PROTECTION
APPLICATION FOR CERTIFICATE TO OPERATE CONTROL APPARATUS OR EQUIPMENT.

TO: New Jersey State Department of Environmental Protection
Bureau of Air Pollution Control
P. O. Box 1390
Trenton, New Jersey 08625

Date November 8, 1972

Use Instructions, Air-D-14

Sec. A	1. Reference Permit No. <u>P-7669</u> SIC No. <u>2833</u>
	2. Full Business Name <u>S.B. Penick, a Unit of CPC International</u>
	3. Address of equipment and/or control apparatus: <u>158</u> <u>Mt. Olivet Ave.,</u> <u>Newark,</u> <u>Essex</u> No. Street Municipality County
	4. Location on premises (Bldg., Dept., area, etc.) <u>Bldg. 27</u>
Sec. B	1. Identify process equipment <u>Fume Incinerator & Spray Dryer for the production of animal feed grade antibiotics.</u>
	2. List air pollution control apparatus <u>Fume Incinerator</u>
	3. Date equipment to be put in use <u>November 28, 1972</u>
Sec. C	Plant Contact: <u>H. Daners</u> <u>201 243-4662</u> Name (Print or Type) Telephone No. <u>Plant Sup't.</u> - Title Telephone Extension

This application is submitted in accordance with the provisions of N.J.S.A. 26:2C-9.2, and to the best of my knowledge and belief is true and correct.

M. Michiels
Signature - all copies

M. Michiels

Name (Print or Type)

Chief Engineer

Title

Mailing Address, Zip

DO NOT WRITE BELOW

CERTIFICATE TO OPERATE CONTROL APPARATUS OR EQUIPMENT	
TEMPORARY DURATION	5 YEAR DURATION
Certificate No. _____	Certificate No. <u>C-7365</u>
Date Approved _____	Date Approved <u>5-14-73</u>
Expiration date _____	Expiration date <u>5-14-78</u>
Approved by: _____ Supervisor, Permits & Certificates	Approved by: <i>[Signature]</i> Supervisor, Permits & Certificates

NEW JERSEY STATE DEPARTMENT OF HEALTH - Community Health Services
1911 PRINCETON AVENUE, TRENTON, NEW JERSEY 08648

NO 0165

1977

CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 - "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of \$10.00 shall accompany such notification."

Registered as: manufacturer; wholesaler which conducts business at the following locations in this State:

- | | |
|--|---|
| 1. <u>540 New York Ave., Lyndhurst</u> | 4. <u>215-225 Watchung Ave., Orange</u> |
| 2. <u>158 Mt. Olivet Ave., Newark</u> | 5. <u>CPC International Warehouse</u> |
| 3. <u>Taylorstown Rd., Montville</u> | <u>Ridgefield</u> |

Reg. No.

#51

S. B. Penick & Company
A Unit of CPC International, Inc.
1050 Wall St., West
Lyndhurst, NJ 07071
Att: Harold Johnson

ISSUED PURSUANT TO

N.J.S.A. 24:6B

James E. Frey

State Commissioner of Health

EXPIRES

JAN. 31, 1978

DDC-9 Oct. 76

ESTABLISHMENT

INSTITUT für BODENBIOLOGIE
Forschungsanstalt für Landwirtschaft
Braunschweig-Völkenrode

Direktor: Prof. Dr. K.H.Domsch

Institut für Bodenbiologie
Bundesallee 50
3300 Braunschweig

Braunschweig, 5.8.1977

Fernruf 59 63 41

Prof. Ja/Fe

Dr. Küther
Lohmann Tierernährung GmbH
Postfach 446
2190 Cuxhaven

Dear Dr. Küther,

Our investigations have been limited to the study of the inactivation of Tetracyclin, Flavomycin, Zinc Bacitracin and Spiramycin in poultry manure and in a mixture of poultry manure with soil.

As we are being primarily interested in the more stable compounds' (Flavomycin, Tetracyclin) influence on the nitrogen-cycle in the soil, we are for the time being not going to test Virginiamycin.

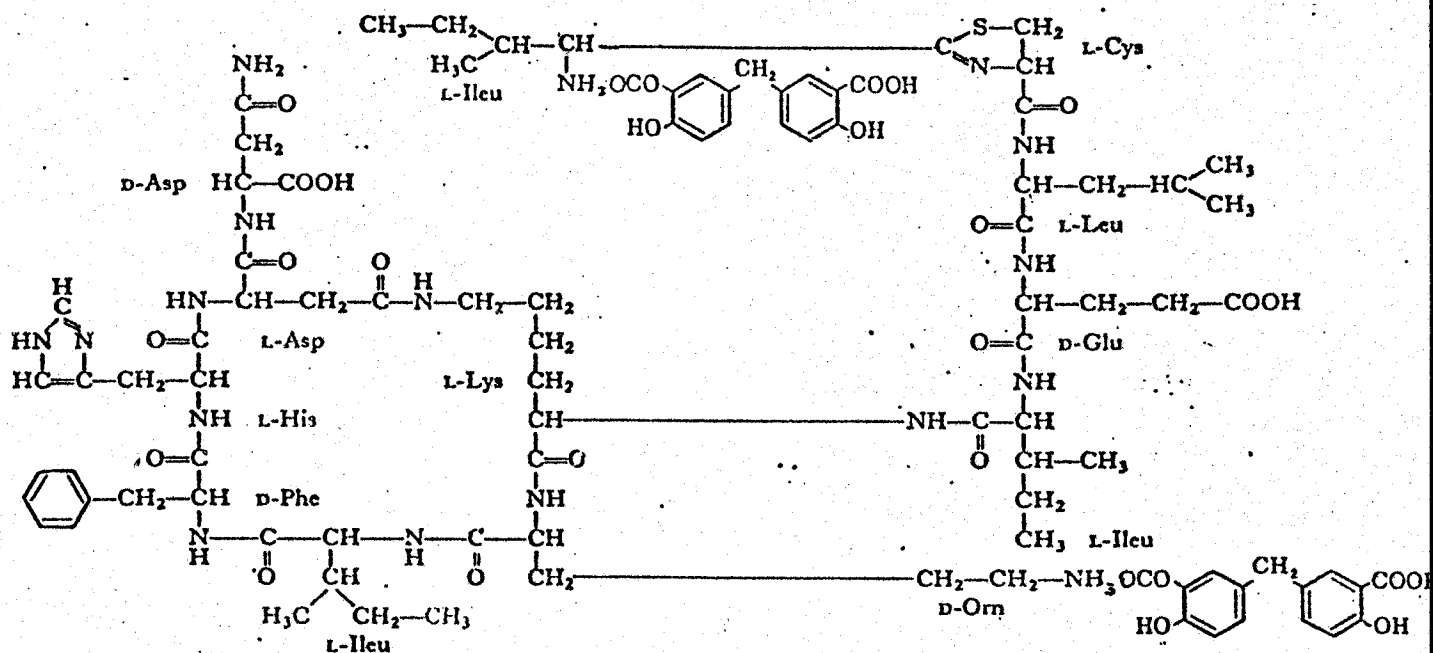
The sample of Zinc Bacitracin obtained from you was completely inactivated within one week when the samples of faeces or faeces/soil mixture were kept in a normal atmosphere or in a nitrogen atmosphere. Further experiments on secondary effects of Zinc Bacitracin in faeces or soil are therefore not necessary.

With kind regards,

Yours sincerely,

signed

(Prof. Dr. G. Jagnow)



BACITRACIN METHYLENE DISALICYLATE

2. i.a. Bacitracin Methylene Disalicylate is the disalicyclic acid salt of the antibiotic bacitracin, a large polypeptide molecule produced by a gram-positive aerobic rod belonging to the *Bacillus licheniformis* group. The molecular weight is 1411.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration
(DESI 0061NV)

BACITRACIN WITH OR WITHOUT PENICILLIN

Drugs for Veterinary Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following preparations:

1. Fortracin-25; each pound contains feed grade bacitracin methylene disalicylate equivalent to 25.0 grams bacitracin (master standard); by S. B. Penick & Co., Antibiotic Feed Division, 100 Church Street, New York, N.Y. 10007.
2. Bio-Best, B-100W; each ounce contains 6.25 grams of bacitracin activity; by Premier Malt Products, Inc., 1037 West McKinley Avenue, Milwaukee, Wis. 53201.
3. Baciferm-10; each pound contains feed grade zinc bacitracin equivalent to 10.0 grams of bacitracin (master standard); by Commercial Solvents Corp., 1331 South First Street, Terre Haute, Ind. 47802.
4. Baciferm-25; each pound contains feed grade zinc bacitracin equivalent to 25.0 grams of bacitracin (master standard); by Commercial Solvents Corp.
5. Baciferm-50; each pound contains feed grade zinc bacitracin equivalent to 40.0 grams bacitracin (master standard); by Commercial Solvents Corp.
6. Baciferm PB-10; each pound contains feed grade zinc bacitracin equivalent to 7.5 grams of bacitracin (master standard) and 2.5 grams of penicillin G master standard as procaine penicillin; by Commercial Solvents Corp.
7. Baciferm PB-25; each pound contains feed grade zinc bacitracin equivalent to 18.75 grams of bacitracin (master standard) and 6.25 grams of penicillin G master standard as procaine penicillin; by Commercial Solvents Corp.
8. Baciferm PB-50; each pound contains feed grade zinc bacitracin equivalent to 37.5 grams of bacitracin (master standard) and 12.5 grams of penicillin G master standard as procaine penicillin; by Commercial Solvents Corp.
9. Baciferm Soluble-50; each pound contains 50 grams of zinc bacitracin (master standard); by Commercial Solvents Corp.
10. Barker's Bartracin-50; each pound contains feed grade bacitracin methylene disalicylate equivalent to 50 grams of bacitracin (master standard); by Barker, Moore & Mein Co., Inc., Post Office Box 12, Lebanon, Pa. 17042.
11. Bartracin; each pound contains the equivalent of 10 grams of bacitracin activity (master standard) as bacitracin methylene disalicylate; by Barker, Moore & Mein Co., Inc.
12. Kemitracin-10; each pound contains 10 grams of bacitracin (from bac-

itracin methylene disalicylate); by Whitmoyer Laboratories, Inc., Myerstown, Pa. 17067.

13. Kemitracin-50; each pound contains 50 grams feed grade bacitracin (from bacitracin methylene disalicylate); by Whitmoyer Laboratories, Inc.

14. Aquatracin; each pound contains 25 grams of bacitracin (from bacitracin methylene disalicylate); by Whitmoyer Laboratories, Inc.

15. Bio-Best B-10; each pound contains bacitracin the equivalent of not less than 10.0 grams bacitracin (master standard); by Premier Malt Products, Inc.

16. Bio-Best B-20; each pound contains bacitracin the equivalent of not less than 20.0 grams bacitracin (master standard); by Premier Malt Products, Inc.

17. Bio-Best B-25; each pound contains bacitracin the equivalent of not less than 25.0 grams bacitracin (master standard); by Premier Malt Products, Inc.

18. Bio-Best B-40; each pound contains bacitracin the equivalent of not less than 40.0 grams of bacitracin (master standard); by Premier Malt Products, Inc.

19. Bio-Best B-50; each pound contains bacitracin the equivalent of not less than 50.0 grams of bacitracin (master standard); by Premier Malt Products, Inc.

20. Bio-Best B-100; each pound contains not less than 100 grams of bacitracin (master standard); by Premier Malt Products, Inc.

21. Kem-Fen-10; each pound contains 7.5 grams bacitracin (from bacitracin methylene disalicylate) and 2.5 grams penicillin (from procaine penicillin); by Whitmoyer Laboratories, Inc.

The Academy evaluated these products as probably effective for the growth claims in poultry and probably not effective for the growth claim in swine or for the therapeutic claims. The Academy stated:

1. Claims made regarding "for prevention of" or "to prevent" should be replaced with "as an aid in the control of" or "to aid in the control of."

2. Each disease claim should be properly qualified as "appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug)." If the disease cannot be so qualified the claim must be dropped.

3. The disease claims for these preparations must be restricted to diseases involving the gastrointestinal tract because of the chemical and pharmacologic properties of bacitracin.

4. Only by controlling pathogenic microorganisms may the use of this product aid in maintaining egg production and hatchability.

5. Claims for growth promotion or stimulation are disallowed and claims for faster gains and/or feed efficiency should be stated as "may result in faster gains and/or improved feed efficiency under appropriate conditions." This is applicable to use in poultry.

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6. The references regarding swine growth are inadequate and more information is needed.

7. Each active ingredient in a preparation containing more than one drug must be effective, or contribute to the effectiveness of the preparation, to warrant acceptance as an active ingredient.

8. The manufacturer's label should warn that treated animals must actually consume enough medicated water or medicated feed to provide a therapeutic dose under the conditions that prevail. As a precaution, the label should state the desired oral dose per unit of animal weight per day for each species as a guide to effective use of the preparation in drinking water or feed.

9. For poultry, it is recommended that a minimum of 25 grams of bacitracin per ton of complete feed is necessary for improving rate of gain and/or feed efficiency.

The Food and Drug Administration concurs in the Academy's evaluation; however, the Administration concludes the appropriate claim for faster weight gains and improved feed efficiency in poultry should be "For increased rate of weight gain and improved feed efficiency for (under appropriate conditions of use)."

This evaluation is concerned only with these drugs' effectiveness and safety to the animal to which administered. It does not take into account the safety for food use of food derived from drug-treated animals. Nothing herein will constitute a bar to further proceedings with respect to questions of safety of the drugs or their metabolites as residues in food products derived from treated animals.

This announcement is published (1) to inform manufacturers of the subject drugs of the findings of the Academy and the Food and Drug Administration and (2) to inform all interested persons that such articles to be marketed must be the subject of approved new animal drug applications and otherwise comply with all other requirements of the Federal Food, Drug, and Cosmetic Act.

Manufacturers of the subject drugs are provided 6 months from the date of publication of this announcement in the FEDERAL REGISTER to submit adequate documentation in support of the labeling used.

Each holder of a new animal drug application which became effective prior to October 10, 1962, is requested to submit updating information as needed to make the application current with regard to manufacture of the drug, including information on drug components and composition, and also including information regarding manufacturing methods, facilities, and controls, in accordance with the requirements of section 512 of the act.

Written comments regarding this announcement, including requests for an informal conference, may be addressed to the Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852.

The manufacturers of the listed drugs have been mailed a copy of the NAS-

NRC report. Any other interested person may obtain a copy by writing to the Food and Drug Administration, Press Relations Staff, 200 C Street SW., Washington, D.C. 20204.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 512, 52 Stat. 1050-51, 82 Stat. 343-51; 21 U.S.C. 352, 360b) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: June 29, 1970.

R. E. DUGGAN,
Acting Associate Commissioner
for Compliance.

(F.R. Doc. 70-9133; Filed, July 16, 1970; 8:45 a.m.)

Product No	NAS NO
1	0-188 thru 0-19
2	0080
3 thru 9	0-112
10	0-076
11	0-077
12	0-074
13	0-075
14	0-062
15 thru 20	0-017
21	0-061