

**ENVIRONMENTAL AND TOXICOLOGICAL ANALYSIS
REPORT FOR PERMA-ZYME™**

December 9, 2002

Prepared by:

**Civil Engineering Research Foundation/International Institute of
Energy Conservation (CERF/IEC)
2131 K Street NW, Suite 700
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1. Introduction

The Civil Engineering Research Foundation/International Institute of Energy Conservation (CERF/IIEC) has signed a contract with Federal Highway Administration to evaluate the performance of soil stabilizers on unpaved roads. Perma-Zyme™ is one of the soil stabilization products selected by CERF/IIEC for evaluation according to the contract requirement. This evaluation includes environmental/toxicological tests, field demonstration and performance evaluation, and long-term performance investigation.

In May 2002, CERF/IIEC and RTI International in Research Triangle Park, NC prepared the *Generic Protocol for Dust Suppression and Soil Stabilization Products* as part of the work for the U.S. Environmental Protection Agency's (EPA) Environmental Technology Verification (ETV) Program. The protocol has been approved by EPA, and evaluation of Perma-Zyme™ is conducted according to this protocol. This report is an analytical summary and theoretical calculation for Perma-Zyme™'s impacts to environment and nearby ecological system, based on the environmental composition and toxicology analysis from state's or EPA licensed laboratories.

CERF/IIEC is a global not-for-profit 501(c)(3) organization, created by the American Society of Civil Engineers (ASCE), focused on constructing an efficient and renewable future. In collaboration with the construction, engineering, and environmental industries, CERF/IIEC promotes and facilitates the advancement of innovation for a sustainable infrastructure. In particular, CERF/IIEC operates innovative technology programs to speed the use of innovation into practice in the areas of transportation, public works, energy systems and applications, and the environment.

2. Laboratory Information

The environmental composition was analyzed at Tri-State Laboratories, Inc. in Youngstown, OH. Tri-State Laboratories is qualified for environmental analysis, and has Certificates of Approval from Ohio Environmental Protection Agency (OhioEPA) (Attachment A).

The toxicological analysis was conducted by ABC Laboratories in Columbia, MO. ABC Laboratories is qualified for toxicological analysis, and has the inspection certificates from US EPA, US Department of Agriculture (USDA), and US Food & Drug Administration (FDA). (Attachment B).

3. Manufacturing and Usage of Perma-Zyme™

According to the manufacturer International Enzymes Inc., Perma-Zyme™ is formulated with enzyme-rich materials that are manufactured through a natural fermentation process using cane sugars and other natural organic compounds. When mixed with water and applied during compaction, Perma-Zyme™ acts upon the soil's organic fines through a catalytic bonding process producing a strong cementation effect. The result is a durable and water-resistant mix that can be used in any climatic environment as a sub-base or as a primary surface.

Before applied into the soil, Perma-Zyme™ is diluted with water. The dilution rate is 1:1,750 (v/v), but it may vary according to the soil moisture. Since the specific gravity of Perma-Zyme™ is 1.4146, the Perma-Zyme™ concentration in the application mixture is approximately 810 mg/L if the dilution rate is 1:1,750 (v/v). The Perma-Zyme™ Application Mixture will be sprayed onto the soil, which has been treated with water to get the desired moisture. The soil is mixed with Perma-Zyme™, windrowed and compact. The final application of Perma-Zyme™ is a gallon for every 165 cubic yard of soil. Most of the soil's specific gravities range from 2.6 – 2.8, the Perma-Zyme™ concentration in treated soil is about 17.3 mg/kg.

4. Physical Properties of Perma-Zyme™

Perma-Zyme™ is a brown, non-corrosive, non-flammable, viscous fluid with slight sweet smell. The physical properties of Perma-Zyme™ are summarized in Table 4-1.

Table 4-1. Physical Properties of Perma-Zyme™

Color	Smell	Flammability	Corrosivity	Specific Gravity
Brown	Slight sweet smell	Non-flammable	No corrosive	1.4146

5. Environmental Composition Results

According to the manufacturing information provided by International Enzyme, Perma-Zyme™ is made of organic materials. The environmental composition analysis consists organic content analyses and toxic chemical analyses. The organic content analytical items are biological oxygen demand (BOD) and chemical oxygen demand (COD). The toxic chemical analyses include metals, herbicides/pesticides, polynuclear aromatic hydrocarbons (PAH), semi-volatile organic compounds (SVOC), and volatile organic compounds (VOC).

Table 5-1 through Table 5-6 show the concentrations of each item in pure Perma-Zyme™ and soil after a standard application. The concentrations in pure Perma-Zyme™ are directly from the laboratory analytical data. The concentrations in soil are calculated based on the 17.3 mg/kg of Perma-Zyme™ in soil.

Table 5-1 Organic Contents in Different Media

Analyte	EPA Method	Perma-Zyme™ (mg/L)	Soil (mg/kg)
BOD	405.1	600,000	7.34
COD	410.4	1,100,000	13.45

Table 5-2 Metal Concentrations in Different Media

Analyte	EPA Method	Perma-Zyme™ (mg/kg)	Soil (mg/kg)
Aluminum	200.7	2.4	0.0415
Antimony	200.7	ND	ND
Arsenic	200.7	ND	ND
Barium	200.7	2.71	0.0469
Beryllium	200.7	ND	ND
Cadmium	200.7	ND	ND
Chromium	200.7	ND	ND
Copper	200.7	ND	ND
Iron	200.7	12.6	0.2180
Lead	200.7	ND	ND
Manganese	200.7	1.35	0.0234
Mercury	200.7	0.003	0.0001
Nickel	200.7	ND	ND
Selenium	200.7	ND	ND
Silver	200.7	ND	ND
Thallium	200.7	ND	ND
Zinc	200.7	2.85	0.0493

Note: ND – non-detected

Table 5-3 Herbicides/Pesticides Contents in Different Media

Analyte	EPA Method	Perma-Zyme™ (mg/kg)	Soil (mg/kg)
2,4-D	8270	ND	ND
Silver	8270	ND	ND
Technical chlordane	8270	ND	ND
Endrin	8270	ND	ND
Heptachlor	8270	ND	ND
Lindane	8270	ND	ND
Methoxychlor	8270	ND	ND
Toxaphene	8270	ND	ND

Note: ND – non-detected

Table 5-4 PAH Contents in Different Media

Analyte	EPA Method	Perma-Zyme™ (mg/kg)	Soil (mg/kg)
Acenaphthlene	8270	ND	ND
Acenaphthylene	8270	ND	ND
Anthracene	8270	ND	ND
Benzo[a]anthracene	8270	ND	ND
Benzo[a]pyrene	8270	ND	ND
Benzo[b]fluoranthene	8270	ND	ND
Benzo[g,h,l]perylene	8270	ND	ND
Benzo[k]fluoranthene	8270	ND	ND
Chrysene	8270	ND	ND
Dibenzo[a,h]anthracene	8270	ND	ND
Fluoranthene	8270	ND	ND
Fluorene	8270	ND	ND
Indeno(1,2,3-cd)pyrene	8270	ND	ND
Naphthalene	8270	ND	ND
Phenathrene	8270	ND	ND
Pyrene	8270	ND	ND

Note: ND – non-detected

Table 5-5 SVOC Contents in Different Media

Analyte	EPA Method	Perma-Zyme™ (mg/kg)	Soil (mg/kg)
Acenaphthene	8270	ND	ND
Acenaphthylene	8270	ND	ND
Anthracene	8270	ND	ND
Benidine	8270	ND	ND
Benzo [a] anthracene	8270	ND	ND
Benzo [a] pyrene	8270	ND	ND
3,4-Benzofluoranthene	8270	ND	ND
Benzo (g,h,l) perylene	8270	ND	ND
Benzo (b) fluoranthene	8270	ND	ND
Benzo (k) fluoranthene	8270	ND	ND
Bis (2-chloroethoxy) methane	8270	ND	ND
Bis (2-chloroethyl) ether	8270	ND	ND
Bis (2-chloroisopropyl) ether	8270	ND	ND
Bis (2-ethylhexyl) phthalate	8270	ND	ND
4-Bromophenyl phenyl ether	8270	ND	ND
Butyl benzyl phthalate	8270	ND	ND
2-Chloronaphthalene	8270	ND	ND
4-Chlorophenyl phenyl ether	8270	ND	ND
Chrysene	8270	ND	ND
Dibenzo [a,h] anthracene	8270	ND	ND
1,2-Dichlorobenzene	8270	ND	ND
1,3-Dichlorobenzene	8270	ND	ND
1,4-Dichlorobenzene	8270	ND	ND
3,3'-Dichlorobenzidine	8270	ND	ND
Diethyl phthalate	8270	ND	ND

Table 5-5 SVOC Contents in Different Media (Continuing)

Dimethyl phthalate	8270	ND	ND
Di-n-butyl phthalate	8270	ND	ND
2,4-Dinitrotoluene	8270	ND	ND
2,6-Dinitrotoluene	8270	ND	ND
Di-n-octyl phthalate	8270	ND	ND
1,2-Diphenylhydrazine (as azobenzene)	8270	ND	ND
Fluoranthene	8270	ND	ND
Fluorene	8270	ND	ND
Hexachlorobenzene	8270	ND	ND
Hexachlorobutadiene	8270	ND	ND
Hexachlorocyclopentadiene	8270	ND	ND
Hexachloroethane	8270	ND	ND
Indeno (1,2,3-cd)pyrene	8270	ND	ND
Isophorone	8270	ND	ND
Naphthalene	8270	ND	ND
Nitrobenzene	8270	ND	ND
N-Nitrosodimethylamine (as diphenylamine)	8270	ND	ND
N-Nitrosodi-n-propylamine	8270	ND	ND
N-Nitrosodiphenylamine	8270	ND	ND
Phenanthrene	8270	ND	ND
Pyrene	8270	ND	ND
1,2,4-Trichlorobenzene	8270	ND	ND
2-Chlorophenol	8270	ND	ND
2,4-Dichlorophenol	8270	ND	ND
2,4-Dimethylphenol	8270	ND	ND
4,6-Dinitro-o-cresol	8270	ND	ND
2,4-Dinitrophenol	8270	ND	ND
2-Methyl phenol	8270	ND	ND
3&4-Methyl phenol	8270	ND	ND
2-Nitrophenol	8270	ND	ND
4-Nitrophenol	8270	ND	ND
Pentachlorophenol	8270	ND	ND
Phenol	8270	ND	ND
2,4,5- Trichlorophenol	8270	ND	ND
2,4,6- Trichlorophenol	8270	ND	ND

Note: ND – non-detected

Table 5-6 VOC Contents in Different Media

Analyte	EPA Method	Perma-Zyme™ (mg/kg)	Soil (mg/kg)
Acetone	8260	ND	ND
Benzene	8260	ND	ND
Bromobenzene	8260	ND	ND
Bromochloromethane	8260	ND	ND
Bromodichloromethane	8260	ND	ND
Bromoform	8260	ND	ND
Bromomethane	8260	ND	ND
2-Butanone	8260	10,674	184.7
n-Butylbenzene	8260	ND	ND
sec-Butylbenzene	8260	ND	ND
tert-Butylbenzene	8260	ND	ND
Carbon Tetrachloride	8260	ND	ND
Chlorobenzene	8260	ND	ND
Chloroethane	8260	ND	ND
Chloroform	8260	ND	ND
Chloromethane	8260	ND	ND
2-Chlorotoluene	8260	ND	ND
4-Ch'orotoluene	8260	ND	ND
1,2-Dibromo-3-chloropropane	8260	ND	ND
Dibromochloromethane	8260	ND	ND
1,2-Dibromoethane	8260	ND	ND
Dibromomethane	8260	ND	ND
1,2-Dichlorobenzene	8260	ND	ND
1,3-Dichlorobenzene	8260	ND	ND
1,4-Dichlorobenzene	8260	ND	ND
Dichlorodifluoromethane	8260	ND	ND
1,1-Dichloroethane	8260	ND	ND
1,2-Dichloroethane	8260	ND	ND
1,1,-Dichloroethene	8260	ND	ND
cis-1,2-Dichloroethene	8260	ND	ND
trans-1,2-Dichloroethene	8260	ND	ND
1,2-Dichloropropane	8260	ND	ND
1,3-Dichloropropane	8260	ND	ND
2,2-Dichloropropane	8260	ND	ND
1,1-Dichloropropene	8260	ND	ND
Ethyl Benzene	8260	ND	ND
Hexachlorobutadiene	8260	ND	ND
2-Hexanone	8260	ND	ND
Isopropylbenzene	8260	ND	ND
p-Isopropyltoluene	8260	ND	ND
Methylene Chloride	8260	ND	ND
Methyl Isobutyl Ketone	8260	ND	ND
Naphthalene	8260	ND	ND
n-Propylbenzene	8260	ND	ND
Styrene	8260	ND	ND
1,1,1,2-Tetrachloroethane	8260	ND	ND

Table 5-6 VOC Contents in Different Media (Continuing)

1,1,2,2-Tetrachloroethane	8260	ND	ND
Tetrachloroethene	8260	ND	ND
Toluene	8260	ND	ND
1,2,3- Trichlorobenzene	8260	ND	ND
1,2,4- Trichlorobenzene	8260	ND	ND
1,1,1- Trichloroethane	8260	ND	ND
1,1,2- Trichloroethane	8260	ND	ND
Trichloroethene	8260	ND	ND
Trichlorofluoromethane	8260	ND	ND
1,2,3- Trichloropropane	8260	ND	ND
1,2,4- Trimethylbenzene	8260	ND	ND
1,3,5- Trimethylbenzene	8260	ND	ND
Vinyl Chloride	8260	ND	ND
m,p-Xylene	8260	ND	ND
o-Xylene	8260	ND	ND

Note: ND – non-detected

The above tables indicate that seven chemicals and BOD/COD were detected in Perma-Zyme™. The chemical concentrations in soil are compared with Risk-Based Concentrations (RBC) in residential soil, which was developed by US EPA as a screen level for contaminants on a concerned site. Table 5-7 compares RBC values and chemical concentrations in soil caused by Perma-Zyme™ application.

Table 5-7 RBC Values and Soil Concentrations

Chemical	RBC Level in Residential Soil (mg/kg)	Chemical in Soil (mg/kg)
BOD	N/A	7.34
COD	N/A	13.45
Aluminum	48,000	0.0415
Barium	5,500	0.0469
Iron	23,000	0.2180
Manganese	1,600	0.0234
Mercury	7.8	0.0001
Zinc	23,000	0.0493
2-Butanone	47,000	184.7

BOD/COD are two major indicators for organic component contents. The BOD/COD values are relative high in the soil due to the fact that Perma-Zyme™ is made from cane sugar. During the manufacturing of Perma-Zyme™, cane sugar is used as raw material and goes through fermentation. The additives are added to the fermentation products, which produces Perma-Zyme™.

From Table 5-7, it can be found that all detected chemical concentrations are significant lower compared with the RBC levels in residential soil, which means that application of Perma-Zyme™ does not increase risk level of soils. Therefore, Perma-Zyme™ is safe for use in the term of environmental impact.

6. Toxicological Analysis Results

In this particular toxicological test, LC₅₀ is used in the laboratory to indicate the toxicity of pure Perma-Zyme™ in water, according to Method EPA/600/4-90/027F and EPA/600/4-91/002 for acute and chronic toxicity, respectively. LC₅₀ means lethal concentration in water that kills 50% of small aquatic creatures used in the test. The toxicity analytical results are listed in Table 6-1.

Table 6-1 Toxicity Analytical Results

Pure Perma-Zyme™ Concentration (mg/L)	Percent Mortality					
	Ceriodaphnia Dubia		Fathead Minnow		Americamysis Bahia	
	Acute	Chronic	Acute	Chronic	Acute	Chronic
Control	0	0	0	3	0	15
0.13	-	-	-	-	-	17
0.25	-	-	-	-	-	25
0.5	-	-	-	-	-	15
1.0	-	-	-	-	0	10
1.3	0	0	0	0	-	-
2.0	-	-	-	-	65	35
2.5	0	0	0	3	-	-
4.0	-	-	-	-	90	-
5.0	-	0	5	13	-	-
8.0	-	-	-	-	100	-
10.0	0	80	35	100	-	-
16.0	-	-	-	-	100	-
20.0	80	100	100	100	-	-
40.0	100	-	-	-	-	-

According to EPA-540-9-85-006, suggested toxicity criteria for materials are listed in Table 6-2.

Table 6-2 Toxicity Categories

LC ₅₀ (mg/L)	Category Description
<0.1	Very highly toxic
0.1 – 1	Highly toxic
1 – 10	Moderately toxic
10 –100	Slightly toxic
>100	Practically non-toxic

If 100 mg Perma-Zyme™ Application Mixture (containing 810 mg/L pure Perma-Zyme™) is diluted with 1 liter control solution, it generates 100 mg/L of Perma-Zyme™ Application Mixture solution. This solution contains 0.081 mg/L pure Perma-Zyme™. From Table 6-1, it can be found that all the toxicity analysis results will be less than 50% at the Perma-Zyme™ concentration of 0.081 mg/L; therefore, the LC₅₀ values for Perma-Zyme™ Application Mixture should be greater than 100 mg/L.

The LC₅₀ values and toxicity categories for pure Perma-Zyme™ and Perma-Zyme™ Application Mixture are summaries in Table 5-3.

Table 6-3 LC₅₀ and Toxicity Category

	Pure Perma-Zyme™		Perma-Zyme™ Application Mixture	
	LC ₅₀ (mg/L)	Toxicity Category	LC ₅₀ (mg/L)	Toxicity Category
Ceriodaphnia Dubia acute	16.2	Slightly toxic	>100	Practically non-toxic
Ceriodaphnia Dubia chronic	8.1	Moderately toxic	>100	Practically non-toxic
Fathead Minnow acute	10.7	Slightly toxic	>100	Practically non-toxic
Fathead Minnow chronic	6.4	Moderately toxic	>100	Practically non-toxic
Americamysis Bahia acute	1.7	Moderately toxic	>100	Practically non-toxic
Americamysis Bahia chronic	>2	Moderately toxic	>100	Practically non-toxic

From Table 6-3, it can be found that pure Perma-Zyme™ is either slightly toxic or moderately toxic in different testing methods. While, Perma-Zyme™ Application Mixture is practically non-toxic in all cases.

7. Conclusion

Based on the calculation and discussion in Sections 5 and 6, the following conclusions can be drawn:

- There are seven chemicals found in Perma-Zyme™, which are listed in EPA's RBC table.
- After Perma-Zyme™ is applied in soil, all seven chemicals' concentrations in soil will be significant lower than the RBC levels in residential soil, which means that application of Perma-Zyme™ does not increase risk level of soils.
- Pure Perma-Zyme™ is either slightly toxic or moderately toxic according to different toxicological analyses.
- Perma-Zyme™ Application Mixture is practically non-toxic in all the toxicological analyses.

Attachment A

Certificates of Approval of Tri-State Laboratories

OhioEPA

certificate of approval

This certifies that the Ohio Environmental Protection Agency, having primary enforcement responsibility for the Safe Drinking Water Act, has evaluated and approved the performance of Microbiological analyses on potable water by:

Tri-State Laboratories, Inc.

by the following laboratory analyst:

Jody Kapadia

The evaluation has been conducted in accordance with The Ohio Revised Code, Section 6109.04 by:

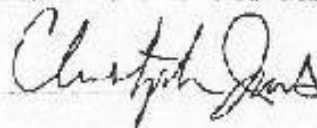
Todd W. Didlack, Laboratory Certification Officer

Pursuant to this Approval, The Ohio Environmental Protection Agency accepts as valid the results of the following analyses on potable water:

Total Coliform and *E. coli* by MMO-MUG (9223)

This certificate may be revoked for failure to conform to the provisions of the Ohio Revised Code, failure to generate acceptable results on performance evaluations, failure to maintain an acceptable laboratory facility in accordance with plan approval requirements, failure to maintain laboratory records, failure to report the results of analyses conducted on public water systems and source waters by personnel not certified for such analyses. This certificate remains the property of the State of Ohio and shall be surrendered to the Director of the Ohio EPA or his authorized representative upon revocation.

Date of Issue: April 17, 2002
Date of Expiration: November 21, 2002
Approval Number: B98



Ohio EPA

certificate of approval

This certifies that the Ohio Environmental Protection Agency, having primary enforcement responsibility for the Safe Drinking Water Act, has evaluated and approved the performance of Chemical analyses on potable water by:

Tri-State Laboratories

by the following laboratory analyst:

Jody Kapadia

The evaluation has been conducted in accordance with The Ohio Revised Code, Section 6109.04 by:

James D. Dolfi and Charles K. Vasulka, Laboratory Certification Officers

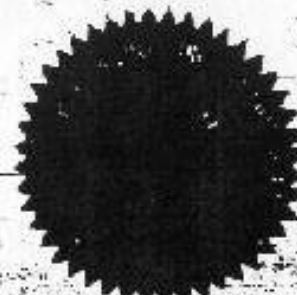
Pursuant to this Approval, The Ohio Environmental Protection Agency accepts as valid the results of the following analyses on potable water:

**Turbidity (SM 2130-B); pH (SM 4500-H+); Hardness (SM 2340-C); Nitrate (353.2);
Phosphate (SM 4500 P-E); Fluoride (SM 4500 F-C); TDS (SM 2540-C)**

This certificate may be revoked for failure to conform to the provisions of the Ohio Revised Code, failure to generate acceptable results on performance evaluations, failure to maintain an acceptable laboratory facility in accordance with plan approval requirements, failure to maintain laboratory records, failure to report the results of analyses conducted on public water systems and source waters by personnel not certified for such analyses. This certificate remains the property of the State of Ohio and shall be surrendered to the Director of the Ohio EPA or his authorized representative upon revocation.

Date of Issue: December 18, 2001
Date of Expiration: December 10, 2002
Approval Number: 1549

Christopher Jones



001-01-02 04:32 PM TRI STATE LABORATORIES 0301272204 P.03



certificate of approval

This certifies that the Ohio Environmental Protection Agency, having primary enforcement responsibility for the Safe Drinking Water Act, has evaluated and approved the performance of Chemical analyses on potable water by:

Tri-State Laboratories

by the following laboratory analyst:

Donna Haworth

The evaluation has been conducted in accordance with the Ohio Revised Code, Section 6109.04 by:

James D. Dolli and Charles K. Vasulka, Laboratory Certification Officers

Pursuant to this Approval, the Ohio Environmental Protection Agency accepts as valid the results of the following analyses on potable water:

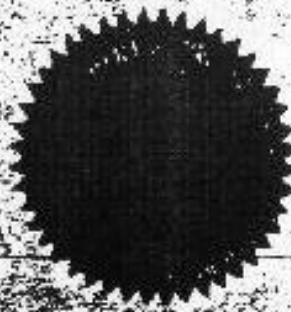
pH (SM 9500-H+); Fluoride (SM 4500 F-C); Sulfate (SM 4500 SO₄-D)

This certificate may be revoked for failure to conform to the provisions of the Ohio Revised Code, failure to generate acceptable results on performance evaluations, failure to maintain an acceptable laboratory facility in accordance with plan approval requirements, failure to maintain laboratory records, failure to report the results of analyses conducted on public water systems and source waters by personnel not certified for such analyses. This certificate remains the property of the State of Ohio and shall be surrendered to the Director of the Ohio EPA or his authorized representative upon revocation.

Date of Issue: December 18, 2001

Date of Expiration: December 10, 2002

Approval Number: 1249



OCT-31-02 04:2 PM TRI STATE LABORATORIES 3387573204

OhioEPA

certificate of approval

This certifies that the Ohio Environmental Protection Agency, having primary enforcement responsibility for the Safe Drinking Water Act, has evaluated and approved the performance of Chemical analyses on potable water by:

Tri-State Laboratories

by the following laboratory analyst:

Scott Bolam

The evaluation has been conducted in accordance with The Ohio Revised Code, Section 6109.04 by:

James D. Dolfi and Charles K. Vasilka, Laboratory Certification Officers

Pursuant to this Approval, The Ohio Environmental Protection Agency accepts as valid the results of the following analyses on potable water:

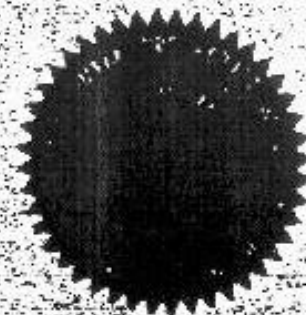
pH (SM 4500-H+); Nitrate (353.2); Lead (SM 3113-B); Copper, Iron, Manganese (SM 3111-B)

This certificate may be revoked for failure to conform to the provisions of the Ohio Revised Code, failure to generate acceptable results on performance evaluations, failure to maintain an acceptable laboratory facility in accordance with plan approval requirements, failure to maintain laboratory records, failure to report the results of analyses conducted on public water systems and source waters by personnel not certified for such analyses. This certificate remains the property of the State of Ohio and shall be surrendered to the Director of the Ohio EPA or his authorized representative upon revocation.

Date of Issue: December 18, 2001

Date of Expiration: December 10, 2002

Approval Number: 1549



Attachment B

Qualification of ABC Laboratories



United States Department of Agriculture
Animal and Plant Health Inspection Service

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INSPECTION REPORT

A B C LABORATORIES INC.

Customer ID: 1598

Certificate: 43-R-0108

Site: 001

ABC LABORATORIES

Inspection

Type: ROUTINE INSPECTION

Date: SEP-17-2002

7200 E ABC LN
COLUMBIA, MO 65202

This inspection was conducted by Noel Premkumar, Director, Jessica Ambroz, WCLC owner, and Dr. Jami Niemann, VMD.

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.

COPY

Prepared By:

Jamilon Niemann, DVM

JAMILON NIEMANN, USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER, Inspector (D: #05)

Date:

SEP-17-2002

Received By:

Noel Premkumar

NOEL PREMOKUMAR

Date:

SEP-17-2002

Title: DIRECTOR

STATE OF MICHIGAN AND AFFILIATED
 DEPARTMENT OF HEALTH AND HUMAN SERVICES
 PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION

OFFICE ADDRESS AND PHONE NO. 1157 P 17
 P.O. Box 18500
 Lansing, Michigan 48901
 Lansing, Michigan 48901

(913) 752-2100

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED <i>Jack Hruschky</i>	PERIOD OF INSPECTION <i>2/12-14/89</i>	DATE RECEIVED
TITLE OF INDIVIDUAL <i>President + CEO</i>	FIRM ESTABLISHMENT (SIC CODE) <i>Contract Lab</i>	
FIRM NAME <i>R/E Laboratories Inc</i>	NAME OF FIRM BRANCH OR UNIT INSPECTED <i>Same</i>	
STREET ADDRESS <i>1200 E. 950 Ave</i>	STREET ADDRESS OF PREMISES INSPECTED <i>Same</i>	
CITY AND STATE (Zip) <i>Columbia Mo 65202</i>	CITY AND STATE (Zip) <i>Same</i>	

CONTENT OF INSPECTION OF YOUR FIRM (PLEASE SUMMARIZE)

① The calibration of both Duette Dissolution apparatus (GMP B1 and GMP B2) is inadequate. The firm only calibrates using Prednisone calibration tablets. The USP requires both Prednisone (Dissolving) Tablets and Felipristin Acid (Dissolving) Tablets ^{and} _{for} calibration.

Correction of items promised by August 1, 1989.

COPY

SEE REVERSE OF THIS PAGE	INSPECTOR'S SIGNATURE <i>Robert P. Whisenand</i>	NAME OF THE FIRM AND (IF KNOWN) CONTACT PERSON <i>R/E Laboratories Inc. Robert P. Whisenand</i>	DATE ISSUED <i>9-14-89</i>
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